

SANOFI-AVENTIS
Form 20-F
April 11, 2005
Table of Contents

As filed with the Securities and Exchange Commission on April 11, 2005

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 20-F

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year ended December 31, 2004

Commission File Number: 001-31368

Sanofi-Aventis

(exact name of registrant as specified in its charter)

N/A

(translation of registrant's name into English)

France

(jurisdiction of incorporation)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

174, avenue de France, 75013 Paris, France

(address of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Securities:	Name of each exchange on which registered:
American Depositary Shares, each representing one-half of one ordinary share, nominal value 2 per share	New York Stock Exchange
Ordinary shares, nominal value 2 per share	New York Stock Exchange (for listing purposes only)

Securities registered pursuant to Section 12(g) of the Act:

American Depositary Shares, each representing one quarter of a Participating Share Series A, per value 70.89 per share (removed from listing and registration on the New York Stock Exchange effective July 31, 1995).

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

**The number of outstanding shares of each of the issuer's classes of capital or
common stock as of December 31, 2004 was:**

ordinary shares: 1,411,404,317

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 Item 18 x

Table of Contents**TABLE OF CONTENTS**

<u>Part I</u>		
Item 1.	<u>Identity of Directors, Senior Management and Advisers</u>	1
Item 2.	<u>Offer Statistics and Expected Timetable</u>	1
Item 3.	<u>Key Information</u>	1
	<u>A. Selected Financial Data</u>	1
	<u>B. Capitalization and Indebtedness</u>	3
	<u>C. Reasons for Offer and Use of Proceeds</u>	3
	<u>D. Risk Factors</u>	4
Item 4.	<u>Information on the Company</u>	13
	<u>A. History and Development of the Company</u>	14
	<u>B. Business Overview</u>	16
	<u>C. Organizational Structure</u>	57
	<u>D. Property, Plant and Equipment</u>	57
Item 5.	<u>Operating and Financial Review and Prospects</u>	61
Item 6.	<u>Directors, Senior Management and Employees</u>	96
	<u>A. Directors and Senior Management</u>	96
	<u>B. Compensation</u>	107
	<u>C. Board Practices</u>	109
	<u>D. Employees and profit sharing</u>	111
	<u>E. Share ownership</u>	113
Item 7.	<u>Major Shareholders and Related Party Transactions</u>	115
	<u>A. Major Shareholders</u>	115
	<u>B. Related Party Transactions</u>	117
	<u>C. Interests of Experts and Counsel</u>	117
Item 8.	<u>Financial Information</u>	118
	<u>A. Consolidated Statements and Other Financial Information</u>	118
	<u>B. Significant Changes</u>	121
Item 9.	<u>The Offer and Listing</u>	121
	<u>A. Offer and Listing Details</u>	121
	<u>B. Plan of Distribution</u>	122
	<u>C. Markets</u>	122
	<u>D. Selling Shareholders</u>	124
	<u>E. Dilution</u>	124
	<u>F. Expenses of the Issue</u>	124
Item 10.	<u>Additional Information</u>	125
	<u>A. Share Capital</u>	125
	<u>B. Memorandum and Articles of Association</u>	127
	<u>C. Material Contracts</u>	139
	<u>D. Exchange Controls</u>	139
	<u>E. Taxation</u>	139
	<u>F. Dividends and Paying Agents</u>	147
	<u>G. Statement by Experts</u>	147
	<u>H. Documents on Display</u>	147
	<u>I. Subsidiary Information</u>	147
Item 11.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	147
Item 12.	<u>Description of Securities other than Equity Securities</u>	150
<u>Part II</u>		
Item 13.	<u>Defaults, Dividend Arrears and Delinquencies</u>	151
Item 14.	<u>Material Modifications to the Rights of Security Holders</u>	151
Item 15.	<u>Controls and Procedures</u>	151
Item 16.	<u>[Reserved]</u>	151
Item 16 A.	<u>Audit Committee Financial Expert</u>	151
Item 16 B.	<u>Financial Code of Ethics</u>	151

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Item 16 C.	<u>Principal Accountants Fees and Services</u>	152
Item 16 D.	<u>Exemptions from the Listing Standards for Audit Committees</u>	152
Item 16 E.	<u>Purchases of Equity Securities by the Issuer and Affiliated Purchasers</u>	152
<u>Part III</u>		
Item 17.	<u>Financial Statements</u>	153
Item 18.	<u>Financial Statements</u>	153
Item 19.	<u>Exhibits</u>	240
Annex A.	<u>IFRS Reconciliation Note</u>	A-1

Table of Contents

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with French generally accepted accounting principles (French GAAP). French GAAP differs in certain significant respects from U.S. generally accepted accounting principles (U.S. GAAP). For a description of the principal differences between French GAAP and U.S. GAAP, as they relate to us and to our consolidated subsidiaries, and for a reconciliation of our shareholders' equity and net income to U.S. GAAP, see Note G to our consolidated financial statements included at Item 18, of this annual report.

Our results of operations and financial condition as of and for the year ended December 31, 2004 have been significantly impacted by our August 2004 acquisition of Aventis and certain subsequent transactions (including the merger of Aventis with and into our company in December 2004). The results of operations of Aventis for the period between August 20, 2004 and December 31, 2004 have been included in our consolidated income statement and cash flow statement. This resulted in a significant increase in revenues and significant changes in other financial statement items in 2004 compared to 2003. The assets and liabilities of Aventis are also included in our consolidated balance sheet at December 31, 2004. See Item 5. Operating and Financial Review and Prospects.

We have prepared unaudited pro forma income statements for 2004 and 2003 that present our results of operations as if the acquisition had taken place on January 1, 2004 and January 1, 2003 respectively, as well as certain other pro forma income statement information described under Item 5. Operating and Financial Review and Prospects. Because of the significance of the Aventis acquisition, we present certain information in this annual report, such as sales of particular pharmaceutical products, as a percentage of our unaudited pro forma sales, rather than as a percentage of our consolidated sales.

Unless the context requires otherwise, the terms sanofi-aventis, the Company, the Group, we, our or us refer to sanofi-aventis and our consolidated subsidiaries. References to Aventis refer to Aventis and its consolidated subsidiaries for periods prior to August 20, 2004.

All references herein to United States or U.S. are to the United States of America, references to dollars or \$ are to the currency of the United States, references to France are to the Republic of France, and references to euro and are to the currency of the European Union member states (including France) participating in the European Monetary Union.

Brand names appearing in this annual report are trademarks of sanofi-aventis and/or its affiliates, with the exception of:

trademarks used or that may be or have been used under license by sanofi-aventis and /or its affiliates, such as Actonel®, Optinate® and Acrel®, trademarks of Procter & Gamble Pharmaceuticals, Alvesco®, a trademark of Altana Pharma AG, Campto®, a trademark of Kabushiki Kaisha Yakult Honsha, Copaxone®, a trademark of Teva Pharmaceutical Industries, Exubera®, a trademark of Pfizer Products Inc., Genasense®, a trademark of Genta Inc in the United States, Tavanic®, a trademark of Daiichi Pharmaceutical Co. Ltd., Mutagrip®, a trademark of Institut Pasteur, Vasten®, a trademark of E.R. Squibb & Sons, Inc.

trademarks sold by sanofi-aventis and/or its affiliates, such as Altace® a trademark of King Pharmaceuticals in the United States, Arixta® and Fraxiparine®, trademarks of GlaxosmithKline, Cardizem®, a trademark of Biovail in the United States, Hexilate®, a trademark of CSL Ltd., Ionamin®, a trademark of the Medeva Pharmaceutical Manufacturers Inc. except in Canada and Spain,

Edgar Filing: SANOFI-AVENTIS - Form 20-F

StarLink®, a trademark of Bayer AG, Suvenyl®, a trademark of Chugai Pharmaceutical Co. Ltd, Synercid®, a trademark of King Pharmaceuticals.

Cipro® in the U.S. and Aspirine® and Kogenate®, trademarks of Bayer AG, Claritin®, a trademark of Schering Corporation, Ivomec®, Eprinex®, Frontline®, and Heartgard®, trademarks of Merial and Hexavac®, a trademark of Sanofi Pasteur MSD.

Table of Contents

PART I

Item 1. Identity of Directors, Senior Management and Advisers

N/A

Item 2. Offer Statistics and Expected Timetable

N/A

Item 3. Key Information

A. Selected Financial Data

SUMMARY SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA OF SANOFI-AVENTIS AND AVENTIS

The tables below set forth selected consolidated financial data for sanofi-aventis for each of the five years during the period ended December 31, 2004, prepared in accordance with generally accepted accounting principles in France. These financial data are derived from the sanofi-aventis consolidated financial statements, which have been audited by PricewaterhouseCoopers Audit and Ernst & Young Audit, each independent auditors.

You should read the data for 2002, 2003 and 2004 in conjunction with sanofi-aventis's consolidated financial statements (including the notes thereto) in Item 18. Financial Statements and Item 5. Operating and Financial Review and Prospects in this annual report.

Sanofi-aventis reports its financial results in euros and in conformity with French GAAP, with a reconciliation to U.S. GAAP. Sanofi-aventis also publishes condensed U.S. GAAP information. A description of the principal differences between French GAAP and U.S. GAAP as they relate to sanofi-aventis's consolidated financial statements are set forth in Note F to sanofi-aventis's audited consolidated financial statements included in this annual report.

SELECTED UNAUDITED PRO FORMA CONDENSED FINANCIAL INFORMATION

Edgar Filing: SANOFI-AVENTIS - Form 20-F

The following selected unaudited pro forma condensed financial information, which gives effect to the offers and the merger, is presented in euros and reflects the combination of sanofi-aventis and Aventis using the purchase method under French GAAP, as though the public offer and the transaction described in Note D.1 Impact of the acquisition of Aventis of the consolidated financial statements in this report had taken place on January 1, 2003 (in the case of the pro forma statement of income for the year ended December 31, 2003) and January 1, 2004 (in the case of the pro forma statement of income for the year ended December 31, 2004).

In addition, the pro forma adjustments reflect the sale to GlaxoSmithKline of sanofi-aventis's interests in Arixtra[®] and Fraxiparine[®], as well as the sale of Campto[®] to Pfizer Inc and the sale of Aventis Behring to CSL. The pro forma adjustments also include adjustments that have been made to Aventis historical financial statements in order to conform their presentation to the pro forma presentation, and other adjustments, including allocation of the purchase price, which are described in section 5 of the Note D.1 to the consolidated financial statements (Impact of the acquisition of Aventis) included in Item 18. Financial Statements in this report.

This selected unaudited pro forma financial information has been derived from and should be read in conjunction with section 5 unaudited pro forma information in Note D.1 Impact of the acquisition of Aventis included in Item 18. Financial Statements in this report. Amounts are stated in euros.

The selected unaudited pro forma financial information is presented for illustrative purposes only and is not necessarily indicative of the operating results or financial condition of the combined entities that would have been achieved had the offers and the merger been completed during the periods presented, nor is the selected unaudited pro forma financial information necessarily indicative of the future operating results or financial position of the combined entities.

Table of Contents

<i>(in millions of euros, except per share data)</i>	As of and for the year ended December 31,					Pro forma unaudited,	
	2000	2001	2002	2003	2004	2003	2004
Income statement data: (b)							
<i>French GAAP</i>							
Net sales	5,963	6,488	7,448	8,048	15,043	24,296	25,418
Gross profit	4,521	5,235	6,070	6,620	11,290	18,513	19,376
Operating profit	1,577	2,106	2,614	3,075	(305)	7,254	8,163
Net income	985	1,585	1,759	2,076	(3,610)	977	1,706
Earnings per share: basic (a)	1.35	2.17	2.42	2.95	(3.91)	0.72	1.27
Earnings per share diluted						0.70	1.23
Balance sheet data: (b)							
<i>French GAAP</i>							
Property, plant and equipment, net	1,217	1,229	1,395	1,449	5,886		
Total assets	7,845	9,967	9,459	9,749	76,755		
Long-term debt	121	119	65	53	8,638		
Total shareholders' equity	4,304	5,768	6,035	6,323	35,574		
U.S. GAAP Data: (c)							
<i>French GAAP net income</i>	985	1,585	1,759	2,076	(3,610)		
Purchase accounting adjustments	(606)	(445)	(311)	(269)	(100)		
Provisions and other liabilities	(99)	(23)			28		
Stock based compensation (f)	(5)	(8)	(8)	(50)	(111)		
Revenue recognition - U.S. BMS alliance	(8)	(136)	117	33			
Other	104	(42)	31	(16)	(21)		
Income tax effects	221	167	52	91	149		
Subtotal U.S. GAAP adjustments	(393)	(487)	(119)	(211)	(55)		
<i>U.S. GAAP net income</i>	592	1,098	1,640	1,865	(3,665)		
<i>French GAAP shareholders' equity</i>							
Purchase accounting adjustments	9,479	8,927	8,576	8,267	7,930		
Provisions and other liabilities	110	35			28		
Revenue recognition - U.S. BMS alliance	(21)	(160)	(35)				
Other	(168)	(456)	(695)	(635)	(541)		
Income tax effects	(1,563)	(1,365)	(1,282)	(1,219)	(1,376)		
Subtotal U.S. GAAP adjustments	7,837	6,981	6,564	6,413	6,041		
<i>U.S. GAAP shareholders' equity</i>	12,141	12,749	12,599	12,736	41,632		
<i>U.S. GAAP earnings per share</i>							
Basic (d)	0.82	1.52	2.30	2.71	(4.03)		
Diluted (e)	0.82	1.51	2.28	2.70	(4.03)		

(a) Based on the weighted average number of shares outstanding in each year, equal to 731,232,525 shares in 2000, 731,711,225 shares in 2001, 727,686,372 shares in 2002, 702,745,208 shares in 2003, and 923,286,539 in 2004.

(b)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

As discussed in Note B.2 to the consolidated financial statements as of, and for the year ended, December 31, 2004 included in Item 18. Financial Statements in this report, sanofi-aventis changed its method of accounting for liabilities as of January 1, 2002. The impact of this change on shareholders' equity was \$24 million.

- (c) As discussed in Note F.3.1 to sanofi-aventis's consolidated financial statements as of, and for the year ended December 31, 2004, included in Item 18. Financial Statements in this report, sanofi-aventis applied Statement of Financial Accounting Standard 142, Goodwill and Other Intangible Assets, as of January 1, 2002.

Table of Contents

- (d) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 723,095,521 shares in 2000, 720,726,645 shares in 2001, 714,322,379 shares in 2002, 689,018,905 shares in 2003, and 910,261,740 in 2004.
- (e) Based on the weighted average number of shares outstanding in each period used to compute diluted earnings per share, equal to 726,783,765 shares in 2000, 725,665,764 shares in 2001, 718,041,806 shares in 2002, 691,120,198 shares in 2003, and 914,862,511 in 2004.
- (f) As discussed in Note F.1.C to sanofi-aventis's consolidated financial statements as of, and for the year ended December 31, 2004, included in Item 18. Financial Statements in this report, sanofi-aventis voluntarily adopted the fair value recognition provisions of Financial Accounting Standard 123, Accounting for Stock-Based Compensation, as of January 1, 2003.

EXCHANGE RATE INFORMATION*Exchange Rates*

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2000 through March 31, 2005 expressed in U.S. dollar per euro. The information concerning the U.S. dollar exchange rate is based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate). We provide the exchange rates below solely for your convenience. We do not represent that euros were, could have been, or could be, converted into U.S. dollars at these rates or at any other rate. For information regarding the effect of currency fluctuations on our results of operations, see Item 5. Operating and Financial Review and Prospects.

Selected Exchange Rate Information

	Period- end Rate	Average Rate (1)	High	Low
	(U.S. dollar per euro)			
2000	0.94	0.92	1.03	0.83
2001	0.89	0.89	0.95	0.84
2002	1.05	0.95	1.05	0.86
2003	1.26	1.14	1.26	1.04
2004	1.35	1.25	1.36	1.18
Last 6 months				
2004				
October	1.27	1.25	1.28	1.23
November	1.33	1.30	1.33	1.27
December	1.35	1.34	1.36	1.32
2005				
January	1.30	1.31	1.35	1.30
February	1.33	1.30	1.33	1.28
March	1.30	1.32	1.35	1.29

- (1) The average of the Noon Buying Rates on the last business day of each month during the relevant period for year average, on each business day of the month for monthly average.

On April 6, 2005, the Noon Buying Rate was \$1.29 per euro.

B. Capitalization and Indebtedness

N/A

C. Reasons for Offer and Use of Proceeds

N/A

Table of Contents

D. Risk Factors

*Important factors that could cause actual results to differ materially from our expectations are disclosed in this annual report, including without limitation the following risk factors and the factors described under **Cautionary Statement Regarding Forward-Looking Statements** . In addition to the risks listed below, we may be subject to other material risks that are not currently known to us or that we deem immaterial at this time.*

Risks Relating to Our Company

The integration of the new Group's activities presents significant challenges that may result in the combined business not operating as effectively as expected or in the failure to achieve some or all of the anticipated benefits of the business combination.

The benefits and synergies expected to result from the combination of sanofi-aventis and Aventis will depend in part on whether the operations of Aventis can be integrated in a timely and efficient manner with those of sanofi-aventis. Sanofi-aventis faces significant challenges in consolidating sanofi-aventis' functions with those of Aventis, and integrating the organizations, procedures and operations of the two businesses. The integration of the two businesses is complex and time-consuming, and management must dedicate substantial time and resources to it. These efforts could divert management's focus and resources from other strategic opportunities and from day-to-day operational matters during the integration process. Failure to successfully integrate the operations of sanofi-aventis and Aventis could result in delay or the failure to achieve some or all of the anticipated benefits from the business combination, including synergies and other operating efficiencies, and could have an adverse effect on the business, operating results, financial condition or prospects of sanofi-aventis.

We incurred substantial debt in connection with the acquisition of Aventis, which limits our business flexibility and requires us to devote cash resources to debt service payments.

In connection with our acquisition of Aventis, our consolidated financial debt increased substantially, because we incurred new debt to finance the cash portion of the acquisition consideration, and because our consolidated financial debt includes the debt incurred by Aventis prior to the acquisition. As a result, our consolidated financial debt was \$16.0 billion as of December 31, 2004, and our consolidated net financial indebtedness (financial debt less cash and cash equivalents and short term investments excluding treasury shares held in connection with stock option plans) was \$14.2 billion, as of that date, compared to consolidated financial debt of \$0.4 billion and a positive consolidated net cash position of \$2.4 billion as of December 31, 2003. As a result, we must make significant debt service payments to our lenders. Our current debt level could restrict our ability to engage in additional transactions or incur additional indebtedness. For more information on our debt, please see **Item 5. Operating and Financial Review and Prospectus - Liquidity and Capital Resources** in this annual report.

We depend on the United States market for a significant part of our current and future operating results. A failure to continue our strategy of profitable operations in that market could adversely affect our business, results of operations, financial condition or prospects.

We may not achieve our growth strategy if we do not maintain and continue to profitably expand our presence in the United States, the world's largest pharmaceuticals market. We have identified the United States, which accounted for 34.5% of our pro forma net sales in 2004, as a potential major source of continued future growth and plan to capitalize on our direct presence in the United States in the coming years to build

Edgar Filing: SANOFI-AVENTIS - Form 20-F

our leadership in this market. We face a number of challenges in maintaining profitable growth in the United States, including:

The success of the management organization that we have established in the United States.

The targeting of new products and customer markets.

The fact that the United States market is dominated by major U.S. pharmaceutical companies.

Potential changes in health care reimbursement policies and possible cost control regulations in the United States.

Exposure to the euro-dollar exchange rate.

Table of Contents

We depend on third parties for the marketing of some of our products. These third parties may act in ways that could harm our business.

We commercialize some of our products in collaboration with other pharmaceutical companies. For example, we currently have a major collaborative arrangement with Bristol-Myers Squibb for the marketing of Plavix[®] and Aprovel[®] in the United States and several other countries, and co-marketing agreements with Procter & Gamble Pharmaceuticals for the osteoporosis treatment Actonel[®] and Teva for Copaxone[®], as well as an agreement with Merck & Co., Inc. for the distribution of vaccines in Europe. We also have alliances with several Japanese companies for the marketing of our products in Japan. See Item 4. Information on the Company Business Overview Marketing and Distribution. When we commercialize our products through collaboration arrangements, we are subject to the risk that certain decisions, such as the establishment of budgets and promotion strategies, are subject to the control of our collaboration partners, and that deadlocks may adversely affect the activities conducted through the collaboration arrangements. For example, our alliances with Bristol-Myers Squibb are subject to the operational management of Bristol-Myers Squibb in some countries, including the United States. We cannot be certain that our partners will perform their obligations as expected. Further, our partners might pursue their own existing or alternative technologies or product candidates in preference to those being developed or marketed in collaboration with us.

The manufacture of our products is technically complex, and supply interruptions caused by unforeseen events can delay the launch of new products, reduce sales and adversely affect operating results and financial condition.

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. Our vaccine products in particular are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent to the sterile processing of biological materials and the potential for the unavailability in adequate amounts of raw materials meeting our standards. The complexity of these processes as well as strict company and government standards for the manufacture of our products and subject us to the risk of production problems, the investigation and remediation of which can cause production delay and additional expense, lost inventories or sales, and with respect to new products, can potentially delay a planned launch.

We depend on third parties for the manufacturing of the active ingredients for some of our products and for a substantial portion of our specialized components and raw materials.

Third-Party Manufacturing of Active Ingredients. Although our general policy is to manufacture the active ingredients for our products ourselves, we subcontract the manufacture of some of our active ingredients to third parties, which exposes us to the risk of a supply interruption in the event that our suppliers experience financial difficulties or are unable to manufacture a sufficient supply of our products. The manufacture of the active ingredients for Eloxatine[®] and Xatral[®] and part of the manufacture of the active ingredient for Stilnox[®] is currently done by third parties, as is a part of the chemical activity linked to Lovenox[®]. Additionally, under our collaborative arrangement with Bristol-Myers Squibb, pharmaceutical production of Plavix[®] and Aprovel[®] is conducted partly in sanofi-aventis plants and partly in Bristol-Myers Squibb plants.

Availability of Specialized Components/Raw Materials. Third parties supply us with a substantial portion of our specialized components and raw materials. Some raw materials essential to the manufacture of our products are not widely available from sources we consider reliable for example, there are a limited number of approved suppliers of heparin. Heparin is used in the manufacture of Lovenox[®]. See Item 4. Information on the Company Business Overview Production and Raw Materials for a description of these outsourcing arrangements.

Although we have not experienced any problems in the past, if disruptions were to arise either in the third-party supply of active ingredients or raw materials, this would impact our ability to sell our products in the quantities demanded by the market, and could damage our reputation and

Edgar Filing: SANOFI-AVENTIS - Form 20-F

relationships with our customers. Even though we aim to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at a second or third facility when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable. Any of these factors could adversely affect our business, operating results or financial condition.

Table of Contents

Our collaborations with third parties expose us to risks that they will assert intellectual property rights on our inventions or fail to keep our unpatented technology confidential.

We occasionally provide information and materials to research collaborators in academic institutions or other public or private entities, or request them to conduct tests to investigate certain materials. In all cases we enter into appropriate confidentiality agreements with such entities. However, those entities might assert intellectual property rights with respect to the results of the tests conducted by their collaborators, and might not grant licenses to us regarding their intellectual property rights on acceptable terms.

We also rely upon unpatented proprietary technology, processes, know-how and data that we regard as trade secrets and protect them in part by entering into confidentiality agreements with our employees, consultants and certain contractors. We cannot be sure that these agreements or other trade secret protections will provide meaningful protection, or if they are breached, that we will have adequate remedies. You should read Item 4. Information on the Company Business Overview Patents, Intellectual Property and Other Rights for more information about our patents and licenses.

Claims relating to marketing practices could adversely affect our business, results of operations and financial condition.

The marketing of our products is heavily regulated, and failure to comply fully with applicable regulations could result in civil or criminal actions against us, and under some circumstances potential disqualification from participation in government health programs. Sanofi-aventis and certain of its subsidiaries are under investigation by various government entities, and are defendants in a number of lawsuits, relating to antitrust and/or pricing and marketing practices, including an investigation of alleged underpayment of rebates to U.S. federal health programs. See Note D.20.1(b) to our consolidated financial statements included at Item 18 of this annual report. Because many of these cases allege substantial unquantified damages, including treble damages, and seek significant punitive damages and penalties, it is possible that any final determination of liability could have a material adverse effect on our financial position, results of operations and cash flows.

Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition.

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the U.S. dollar, the British pound, the Japanese yen, and to a lesser extent to currencies in emerging countries. In 2004, 34.5% of our pro forma net sales were realized in the United States. While we incur expenses in those currencies, the impact of these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations. For more information concerning our exchange rate exposure, see Item 11. Quantitative and Qualitative Disclosures About Market Risk.

Risks Relating to Our Industry

We must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments if our products are unsuccessful in clinical trials or fail to receive regulatory approval.

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products. In 2004 on a pro forma basis, we spent 3,961 million on research and development, amounting to approximately 15.6% of our pro forma net sales. Our ongoing investments in new product launches and research and development for future products could produce higher costs without a proportionate increase in revenues.

Table of Contents

The research and development process is lengthy and carries a substantial risk of product failure. If our research and development does not yield sufficient new products that achieve commercial success, our future operating results may be negatively affected.

The research and development process typically takes from 10 to 15 years from discovery to commercial product launch. This process is conducted in various stages, and during each stage there is a substantial risk that we will not achieve our goals and will have to abandon a product in which we have invested substantial amounts.

For example, in order to develop a commercially viable product, we must demonstrate, through extensive pre-clinical and human clinical trials, that the pharmacological compounds are safe and effective for use in humans. There is also no assurance that favorable results obtained in pre-clinical trials will be confirmed by later clinical trials, or that the clinical trials will establish sufficient safety and efficacy data necessary for regulatory approval. In the first quarter, we had 128 compounds in pre-clinical and clinical development in our targeted therapeutic areas, of which 48 were in phase II or phase III clinical trials. For additional information regarding clinical trials and the definition of the phases of clinical trials, see Item 4. Information on the Company Business Overview Research and Development. There can be no assurance that any of these compounds will be proven safe or effective, or that they will produce commercially successful products.

After completing the research and development process, we must invest substantial additional resources seeking to obtain government approval in multiple jurisdictions, with no assurance that approval will be obtained. We must obtain and maintain regulatory approval for our pharmaceutical products from the European Union, the United States and other regulatory authorities before a given product may be sold in its markets and thereafter. The submission of an application to a regulatory authority provides no assurance that the regulatory authority will grant a license to market the product. Each authority may impose its own requirements, including requiring local studies, and may delay or refuse to grant approval, even though a product has already been approved in another country.

In our principal markets, the approval process for one or more indications of a new product is complex and lengthy, and typically takes from six months to two years from the date of application depending on the country. Moreover, if regulatory approval of a product is granted, the approval may place limitations on the indicated uses for which it may be marketed. A marketed product is also subject to continual review even after regulatory approval. Later discovery of previously unknown problems may result in marketing restrictions or withdrawal of the product (as has occurred recently with respect to a number of products marketed by other major pharmaceutical companies), as well as an increased risk of litigation. In addition, we are subject to strict government controls on the manufacture, labeling, distribution and marketing of our products. Each of these factors may increase our costs of developing new products and the risk that we may not succeed in selling them successfully.

If we are unable to protect our proprietary rights, we may not compete effectively or operate profitably.

It is important for our success that we be able to effectively obtain, maintain and enforce our patents and other proprietary rights. Patent law relating to the scope of claims in the pharmaceutical field in which we operate is a continually evolving field of law and can be subject to some uncertainty. Accordingly, we cannot be sure that:

new, additional inventions will be patentable;

patents for which applications are now pending will be issued or reissued to us; or

Edgar Filing: SANOFI-AVENTIS - Form 20-F

the scope of any patent protection will be sufficiently broad to exclude competitors.

Additionally, third parties may challenge the validity of the patents issued or licensed to us, which may result in the invalidation of these rights and the loss of the related sales. We currently have approximately 49,000 patents, patent licenses and patent applications worldwide. Patent litigation is subject to substantial uncertainty, and we cannot be sure how much protection, if any, will be provided by our patents if we attempt to enforce them and they are challenged in court or in other proceedings. Additionally, patent protection is limited in time. To the extent effective patent protection of our products is not maintained, these products will become exposed to competition from generic products. The entry of a generic product into the market typically is followed by a substantial decline in the brand-name product's sales volume and revenues.

Table of Contents

Significant challenges to our proprietary rights include:

In the first half of 2002, two pharmaceutical companies, Apotex and Dr. Reddy's Laboratories, each filed an Abbreviated New Drug Application, or ANDA, with the U.S. Food and Drug Administration, or FDA, seeking to market a generic form of Plavix® in the United States and challenging certain U.S. patents relating to Plavix®. Subsequently, in August 2004, Teva filed an ANDA challenging one of the U.S. patents relating to Plavix®. Similar challenges have been instituted in Canada and Scotland. For additional information regarding ANDAs, see Item 4. Information on the Company Business Overview Regulation. We have filed suit against Apotex, Dr. Reddy's Laboratories and Teva for infringement of our patent rights. See Item 8. Financial Information Consolidated Financial Statements and Other Information Information on Legal and Arbitral Proceedings and Note D.20.1(c) to our consolidated financial statements included in this annual report at Item 18. The Plavix® patent rights are material to our business, and if we were unsuccessful in asserting them or they were deemed invalid, any resulting introduction of a generic version of Plavix® in the U.S. would reduce the price that we receive for this product and the volume of the product that we would be able to sell and could materially adversely affect our business, operating results and financial condition.

As a reference, the pro forma developed sales of Plavix® in 2004 in the United States amounted to 2,289 million out of total worldwide pro forma developed sales of sanofi-aventis of 28,529 million. Pro forma developed sales is a non-GAAP financial measure we use to demonstrate the overall trends for our products in the market, and which consists of pro forma sales of our products, excluding sales to our alliance partners, and of sales that are made through our alliances and which are not included in our consolidated sales. In 2004, sanofi-aventis's share of the profits of the Plavix® and Avapro® joint ventures managed by Bristol-Myers Squibb in North America amounted to 581 million, versus 436 million in 2003. See Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2004 Compared to Year Ended December 31, 2003 herein for additional information as well as a derivation of pro forma developed sales.

We have been notified that seven generic pharmaceutical companies are seeking FDA approval to market generic versions of Allegra® products in the U.S. We have filed patent infringement lawsuits against all of these companies. In June 2003, we were notified that both Amphastar Pharmaceuticals and Teva Pharmaceuticals were seeking approval from the FDA for generic versions of Lovenox® and are challenging the patent protection of this product. We are also involved in litigation challenging the validity, assertibility or enforceability of patents related to a number of other products, and challenges to other products may be expected in the future. See Item 18. Financial Information Consolidated Financial Statements and Other Information Information on Legal and Arbitral Proceedings and Note D.20.1(c) to our consolidated financial statements included in this annual report at Item 18 for additional information.

Our patents may be infringed, or we may infringe the patents of others.

Our competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement, we may file infringement claims, which are expensive and time consuming. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights. This risk is increased by the growth in the number of patent applications filed and patents granted in the pharmaceutical industry.

Product liability claims could adversely affect our business, operating results and financial condition.

Product liability is a significant commercial risk for us, and may become a more significant risk as we expand in the United States (where product liability claims can be particularly costly). Substantial damage awards have been made in certain jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. In addition, some pharmaceutical companies have recently withdrawn products from the market in the wake of significant product liability claims or concerns about potential claims. Although we

Edgar Filing: SANOFI-AVENTIS - Form 20-F

maintain insurance to cover risk of product liability, we cannot be certain that our insurance will be sufficient to cover all potential liabilities. Further, there is a general trend in the insurance industry to exclude certain products from coverage and to reduce insured limits for liabilities arising through joint ventures. Substantial product liability claims, if successful, could adversely affect our business, operating results and financial condition.

Table of Contents

Use of biologically-derived ingredients may face consumer resistance, which could adversely affect sales and cause us to incur substantial costs.

In line with industry practice, we manufacture our vaccines and many of our prescription pharmaceutical products with ingredients derived from animal or plant tissue. Most of these products cannot be made economically, if at all, with synthetic ingredients. We subject our products incorporating these ingredients to extensive tests and believe them to be safe. There have been instances in the past where the use of biologically derived ingredients by sanofi-aventis or its competitors has been alleged to be an actual or theoretical source of harm, including infection or allergic reaction, or instances where production facilities have been subject to prolonged periods of closure because of possible contamination. Such allegations have on occasion lead to damage claims and increased consumer resistance to such ingredients. A substantial claim of harm caused by a product incorporating biologically derived ingredients or a contamination event could lead us to incur potentially substantial costs as a result of, among other things, litigation of claims, product recalls, adoption of additional safety measures, manufacturing delays, investment in consumer education, and development of synthetic substitutes for ingredients of biological origin. Such claims also could generate consumer resistance, with a corresponding adverse effect on sales and operating results.

We face uncertainties over pricing of pharmaceutical products.

The commercial success of our products depends in part on the conditions under which our products are reimbursed. Price pressure is strong due to:

price controls imposed by governments in many countries; and

the tendency of governments and private health care providers to favor generic pharmaceuticals.

Price pressure is considerable in our two largest markets, Europe and the United States, which represented 43.8% and 34.5%, respectively, of our pro forma net sales in 2004. Changes in the pricing environments in the United States or Europe (on an individual country basis) could have a significant impact on our revenues and operating profits. See Item 4. Information on the Company Business Overview Pricing for a description of certain regulatory pricing systems that impact our Group.

Our results may also be adversely affected by parallel imports, a practice by which traders exploit price differentials among markets by purchasing in lower-priced markets for resale in higher-priced markets.

Changes in marketing status or competitive environment of our major products could adversely affect our operating results.

In some cases, pharmaceutical products face the risk of being switched from prescription drug status to over-the-counter (OTC) drug status by national regulatory authorities. OTC drugs may not benefit from the same reimbursement schemes and are generally priced significantly lower than brand-name prescription drugs. The competitive environment of our products could also be adversely affected if generic or OTC versions of competitors' products were to become available.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

For example, Allegra[®], which generated pro forma net sales of 1,502 million in 2004, may face additional price pressure in the United States if it is switched to over-the-counter (OTC) status. In May 2001, a majority of the members of an FDA joint Advisory Committee recommended that Allegra[®] and two competing drugs be switched from prescription to OTC status as requested in a citizen petition filed by certain managed care organizations. The FDA has not publicly acted on the citizen petition, and it is not possible to predict what action, if any, the FDA might take. In November 2002, the FDA approved a change from prescription to OTC status for Claritin[®], a drug competing with Allegra[®], and OTC versions of Claritin[®] now compete with Allegra[®] in the United States.

Table of Contents

Risks from the handling of hazardous materials could adversely affect our operating results.

Pharmaceutical manufacturing activities, such as the chemical manufacturing of the active ingredients in our products and the related storage and transportation of raw materials, products and wastes expose us to various risks, including:

fires and/or explosions from inflammable substances;

storage tank leaks and ruptures; and

discharges or releases of toxic or hazardous substances.

These operating risks can cause personal injury, property damage and environmental contamination, and may result in:

the shutdown of affected facilities and

the imposition of civil or criminal penalties.

The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

Although we maintain property, business interruption and casualty insurance that we believe is in accordance with customary industry practices, we cannot assure you that this insurance will be adequate to cover fully all potential hazards incidental to our business. For more detailed information on environmental issues, see Item 4. Information on the Company Business Overview Health, Safety and Environment.

Environmental liabilities and compliance costs may have a significant adverse effect on our operating results.

The environmental laws of various jurisdictions impose actual and potential obligations on our Group to remediate contaminated sites. These obligations may relate to sites:

that we currently own or operate,

that we formerly owned or operated, or

where waste from our operations was disposed.

These environmental remediation obligations could significantly reduce our operating results. In particular, our accruals for these obligations may be insufficient if the assumptions underlying these accruals prove incorrect or if we are held responsible for additional, currently undiscovered contamination. Any shortfalls could have a material adverse effect on our operating profits. See [Item 4. Information on the Company](#), [Business Overview](#), [Health, Safety and Environment](#) for additional information regarding our environmental policies.

Furthermore, we are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former sanofi-aventis subsidiaries have been named as potentially responsible parties or the equivalent under the U.S. Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as Superfund), and similar statutes in the United States, France, Germany, Brazil and elsewhere. As a matter of statutory or contractual obligation, we and/or our subsidiaries may retain responsibility for environmental liabilities at some of the sites our predecessor companies, our subsidiaries and we demerged, divested or may divest. We are currently involved in litigation with Albemarle and Rhodia over environmental remediation at several sites no longer owned by the Group. An adverse outcome in any of these might have a significant adverse effect on our operating results. See Note D.20.1(d) to the consolidated financial statements included at [Item 18](#) of this annual report.

Finally, stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our Group and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, operating results or financial condition.

Table of Contents

Risks Relating to an Investment in our Shares or ADSs

Foreign exchange fluctuations may adversely affect the U.S. dollar value of our ADSs and dividends (if any).

As a holder of ADSs, you may face exchange rate risk. Our ADSs trade in U.S. dollars and our shares trade in euros. The value of the ADSs and our shares could fluctuate as the exchange rates between these currencies fluctuate. If and when we do pay dividends, they would be denominated in euros. Fluctuations in the exchange rate between the euro and the U.S. dollar will affect the U.S. dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the U.S. dollar price of the ADSs on the New York Stock Exchange, whether or not we pay dividends in addition to the amounts, if any, that you would receive upon our liquidation or upon the sale of assets, merger, tender offer or similar transactions denominated in euros or any other foreign currency other than U.S. dollars.

If you hold ADSs rather than shares it may be difficult for you to exercise some of your rights as a shareholder.

As a holder of ADSs, it may be more difficult for you to exercise your rights as a shareholder than it would be if you directly held shares. For example, if we offer new shares and you have the right to subscribe for a portion of them, the depositary is allowed, in its own discretion, to sell for your benefit that right to subscribe for new shares instead of making it available to you. Also, to exercise your voting rights, as a holder of ADSs, you must instruct the depositary how to vote your shares. Because of this extra procedural step involving the depositary, the process for exercising voting rights will take longer for you, as a holder of ADSs, than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting.

Sanofi-aventis's two largest shareholders own a significant percentage of the enlarged share capital and voting rights of sanofi-aventis.

At December 31, 2004, Total and L'Oréal, our two largest shareholders, held approximately 12.7% and 10.1% of our issued share capital, accounting for approximately 21.4% and approximately 17.1%, respectively, of the voting rights of sanofi-aventis. See Item 7. Major Shareholders and Related Party Transactions - Major Shareholders - Shareholders Agreement.

To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, Total and L'Oréal will remain in a position to exert heightened influence in the election of the directors and officers of sanofi-aventis and in other corporate actions that require shareholders' approval. Continued ownership of a large percentage of the share capital and voting rights of sanofi-aventis by these two principal shareholders, affiliates of whom may also continue to be members of the sanofi-aventis board of directors, may have the effect of delaying, deferring or preventing a future change in the control of sanofi-aventis and may discourage future bids for sanofi-aventis other than with the support of these shareholders.

Sales of our shares that will be eligible for sale in the near future may cause the market price of our shares or ADSs to decline.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Total and L. Oréal are not, to our knowledge, subject to any contractual restrictions on the sale of the shares they hold in our company. Sales of a substantial number of our shares, or a perception that such sales may occur, could adversely affect the market price for our shares and ADSs. See

Item 10. Additional Information – Share Capital – Shares Eligible for Future Sale for a more detailed description of the eligibility of our shares for future sale.

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements. We may also make written or oral forward-looking statements in our periodic reports to the Securities and Exchange Commission on Form 6-K, in our annual report to shareholders, in our proxy statements, in our offering circulars and prospectuses, in press releases and other written materials and in oral statements made by our officers, directors or employees to third parties. Examples of such forward-looking statements include:

projections of operating revenues, net income, net earnings per share, capital expenditures, positive or negative synergies, dividends, capital structure or other financial items or ratios;

statements of our plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition;

statements about our future economic performance or that of France, the United States or any other countries in which we operate; and

statements of assumptions underlying such statements.

Words such as believe, anticipate, plan, expect, intend, target, estimate, project, predict, forecast, guideline, should and intended to identify forward-looking statements but are not the exclusive means of identifying such statements.

Forward-looking statements involve inherent risks and uncertainties. We caution you that a number of important factors could cause actual results to differ materially from those contained in any forward-looking statements. Such factors, some of which are discussed under Risk Factors above, include but are not limited to:

the impact of our acquisition of Aventis;

our ability to continue to maintain and expand our presence profitably in the United States;

the success of our research and development programs;

our ability to protect our intellectual property rights;

the risks associated with reimbursement of healthcare costs and pricing reforms, particularly in the United States and Europe; and

trends in the exchange rate and interest rate environments.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

We caution you that the foregoing list of factors is not exclusive and that other risks and uncertainties may cause actual results to differ materially from those in forward-looking statements.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.

Table of Contents

Item 4. Information on the Company

Introduction

We are a global pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. In 2004, our pro forma net sales were 25,418 million, our pro forma operating profit was 8,163 million and our adjusted pro forma net income was 5,247 million. On the basis of 2004 pro forma net sales, we are the third largest pharmaceutical group in the world and the largest pharmaceutical group in Europe (IMS/GERS year end 2004).

Our business includes two main activities: pharmaceutical (principally prescription drugs) and human vaccines.

In our pharmaceutical activity, we specialize in six therapeutic areas:

Cardiovascular: Our cardiovascular products include two major hypertension treatments: Aprovel[®] and Tritace[®].

Thrombosis: Our thrombosis products include two leading drugs in their categories: Plavix[®], an anti-clotting agent indicated for atherothrombosis, and Lovenox[®], a low molecular weight heparin indicated for deep vein thrombosis.

Metabolic Disorders. Our products for metabolic disorders include Lantus[®], a long acting analogue insulin leader in the branded insulin market, and Amaryl[®], a once-daily sulfonylurea.

Oncology. Our lead products in the strategic oncology market are Taxotere[®], a taxane derivative representing a cornerstone therapy in several cancer types, and Eloxatine[®], an innovative platinum agent, which is a leading treatment of metastatic colorectal cancer.

Central Nervous System, or CNS. Our CNS medicines include Stilnox[®], the world's leading insomnia prescription medication; Copaxone[®], an immunomodulating agent indicated in multiple sclerosis; and Depakine[®], one of the leading epilepsy treatments.

Internal Medicine. In internal medicine, we are present in several fields. In respiratory/allergy, our products include Allegra[®], a non-sedating prescription antihistamine, and Nasacort[®], a local corticosteroid indicated in allergic rhinitis. In urology, we are present with Xatral[®], a leading treatment for benign prostatic hypertrophy. In osteoporosis, we are present with Actonel[®].

Our top fifteen products are Lovenox[®], Plavix[®], Allegra[®], Taxotere[®], Stilnox[®], Eloxatine[®], Tritace[®], Lantus[®], Aprovel[®], Copaxone[®], Amaryl[®], Actonel[®], Depakine[®], Nasacort[®] and Xatral[®], which together accounted for 60.5% of our pro forma net sales for the pharmaceutical activity, or 14,386 million, in 2004.

In the human vaccines activity, we are a major player with leading vaccines in six areas:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Pediatric combination vaccines, an area in which our main products are DAPTACEL[®], Tripedia[®], ActHIB[®], Pentacel and Pediacel[®].

Influenza vaccines, which experienced strong growth in the northern hemisphere with Fluzone[®] and Vaxigrip[®].

Polio vaccines, where our main products IPOL[®] and Imovax[®] Polio are contributing to polio eradication.

Adult and adolescent booster vaccines, which include Adacel, which will be the first trivalent booster.

Meningitis vaccines, where our main products are quadrivalent vaccines Menomune[®] and Menactra[®], (approved by the FDA in January 2005). Menactra[®] provides a longer-lasting immune response.

Travel vaccines, which include a wide range of vaccines.

We have a strong commitment to research and development. We have 27 research centers and over 17,000 employees* devoted to research and development. In the first quarter of 2005, we had a total of 128 compounds in development in our seven therapeutic areas, including 20 for vaccines, 48 of which were in phase II or phase III clinical trials.

* including Vaccines, Industrial Development, Medical/Regulatory staff in subsidiaries.

Table of Contents

Sanofi-aventis was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. We operate under the commercial name sanofi-aventis. Our registered office is located at 174, avenue de France, 75013 Paris, France, and our main telephone number is +33 (1) 53 77 40 00. Our principal U.S. subsidiary's office is located at 300 Somerset Corporate Boulevard, Bridgewater, NJ 08807-2854.

A. History and Development of the Company

Following our acquisition of Aventis in August 2004, sanofi-aventis is the largest pharmaceutical group in Europe and the third largest pharmaceutical group in the world, present in more than 100 countries on five continents and employing over 96,400 people worldwide at year end 2004. The main purpose of the combination of Sanofi-Synthélabo and Aventis was to create a platform for strong, sustainable and profitable growth.

Our legacy companies bring to the Group more than a century of experience in the pharmaceutical industry.

Sanofi-Synthélabo was the result of the 1999 merger of Sanofi and Synthélabo, two major French pharmaceutical companies. Since their merger, Sanofi-Synthélabo had combined the resources of the two legacy companies to expand its global presence, particularly in the United States, and to increase its focus on research and development for products with strong growth potential.

Sanofi was founded in 1973 by Elf Aquitaine, a French oil company, when it took control of the Labaz group (a pharmaceutical company) for diversification purposes. Sanofi launched its first major product on the market, Ticlid®, in 1978. At the time of the merger with Synthélabo in 1999, Sanofi was the second largest pharmaceutical group in France in terms of sales. A majority of its share capital was owned by Elf Aquitaine, which was subsequently acquired by Total. Sanofi made a significant venture into the United States market in 1994, when it acquired the prescription pharmaceuticals business of Sterling Winthrop, an affiliate of Eastman Kodak. Sanofi launched its first major product on the U.S. market, Aprovel®, in 1997, followed by Plavix® in 1998.

Synthélabo was founded in 1970 through the merger of two French pharmaceutical laboratories, Laboratoires Dausse (founded in 1834) and Laboratoires Robert & Carrière (founded in 1899). In 1973, the French cosmetics group L'Oréal acquired the majority of its share capital, and in 1988 Synthélabo launched two major products on the French market: Stilnox® and Xatral®. At the time of the merger with Sanofi, Synthélabo was the third largest pharmaceutical group in France in terms of sales. A majority of its share capital was still owned by L'Oréal. In 1993, Synthélabo launched Stilnox® in the United States under the brand name Ambien®. By 1994, Stilnox® had become the leading insomnia prescription medication worldwide (IMS Health).

The formation of Aventis on December 15, 1999 was the result of the combination of Rhône-Poulenc and Hoechst. The objective of this merger was to create a leader in life sciences both in pharmaceuticals and in agriculture, by bringing together a broad portfolio of activities including among others prescription drugs and vaccines, which became the core business of Aventis. A brief overview of the creation of both Hoechst and Rhône-Poulenc is detailed below with a focus on their pharmaceutical activities.

Hoechst, named for the district in Frankfurt where it was located, traces its origins to the second half of the 19th century, with the German industrial revolution and the emergence of the chemical industry. In the 1950s and 1960s, the company devoted itself primarily to developing its chemical and petrochemical businesses. Increased efforts in research and development and production and distribution contributed to the

Edgar Filing: SANOFI-AVENTIS - Form 20-F

company's internal growth. It also made numerous acquisitions, including Behring and Wacker-Chemie. Already active in pharmaceuticals (notably penicillin), Hoechst strengthened its positions in that industry by taking a majority equity interest in Roussel-Uclaf in 1974. In 1987, confronted with the necessity of developing global operations, Hoechst purchased the U.S.-based Celanese Corporation and in 1995 the U.S. pharmaceutical company Marion Merrell. In 1997, Hoechst bought the outstanding minority interest of Roussel-Uclaf and formed Hoechst Marion Roussel (HMR), its strengthened and reorganized pharmaceutical division. This initial move to restructure the company into the key areas of pharmaceuticals, agricultural chemicals and industrial chemicals enabled it, in 1999, to complete its move to a focus on life sciences and become part of the new company Aventis. Hoechst was especially strong in metabolic disorders with Amaryl[®] and several insulin products, cardiovascular diseases with Tritace[®], respiratory diseases with Allegra[®] and osteoporosis with Actonel[®].

Table of Contents

Rhône-Poulenc was formed in 1928 from the merger of two French companies, a chemical company created by the Poulenc brothers and Société Chimique des Usines du Rhône, which had been founded in 1895. The company's activities in the first half of the 20th century focused on producing chemicals, textiles and pharmaceuticals (acetylsalicylic acid and penicillin). Its international expansion began in 1927 when Poulenc took a majority interest in May & Baker, opening its access to the British Empire (in particular in Asia). In 1948, the company gained a foothold in the North American market by creating Rhodia Inc. It became Rhône-Poulenc S.A. in 1961, was nationalized in 1982 and was subsequently privatized in 1993. Rhône-Poulenc began to focus its activities on life sciences in the 1990s, which led to the successive purchases of Rorer, a U.S. pharmaceutical company acquired in two stages in 1990 and 1997, Institut Mérieux in the area of vaccines in 1994 and the U.K. pharmaceutical company Fisons in 1995. By refocusing on its core businesses of pharmaceuticals, animal and plant health, and custom chemicals, Rhône-Poulenc began the transformation that led to its withdrawal from commodity chemicals in favor of pharmaceuticals and agricultural chemicals. Rhône-Poulenc's main therapeutic fields were thrombosis with Lovenox[®], oncology with Taxotere[®] and Campto[®] (divested in 2004), respiratory diseases with Nasacort[®], and vaccines.

With renewed focus on its pharmaceuticals business, Aventis actively pursued the disposal of most of its non-strategic activities including therapeutic proteins, specialty and industrial chemicals and the crop science business. At the same time, Aventis concentrated on developing blockbusters, such as Lovenox[®], Copaxone[®], Actonel[®], Allegra[®] and Taxotere[®], and on launching innovative drugs such as Lantus[®] and Ketek[®].

The Acquisition

On January 26, 2004, Sanofi-Synthélabo announced a bid to acquire all of the shares of Aventis through mixed exchange/cash tender offers on substantially identical terms in France, Germany and the United States. On April 26, 2004, the managements of Sanofi-Synthélabo and Aventis announced that the Supervisory Board of Aventis had voted to recommend an improved offer to Aventis shareholders. The principal terms of Sanofi-Synthélabo's offers were as follows (as adjusted to account for a divided distribution approved by Aventis subsequent to April 26, 2004):

Standard Entitlement: 5 sanofi-aventis ordinary shares and 115.08 in cash for 6 Aventis ordinary shares (or 0.8333 of a sanofi-aventis ordinary share and 19.18 in cash for each Aventis ordinary share; and 1.6667 sanofi-aventis ADSs and an amount in U.S. dollars equal to 19.18 in cash for each Aventis ADS);

All Stock Election: 1.1600 sanofi-aventis ordinary shares for each Aventis ordinary share (or 2.3200 sanofi-aventis ADSs for each Aventis ADS); and

All Cash Election: 68.11 in cash for each Aventis ordinary share (or an amount in U.S. dollars equal to 68.11 in cash for each Aventis ADS).

On August 20, 2004 Sanofi-Synthélabo acquired control of Aventis upon the settlement of these offers. At that time, Sanofi-Synthélabo changed its registered name to sanofi-aventis and announced that it would open a subsequent offering period for the remaining shares of Aventis. As of September 24, 2004, on the settlement of the purchase and exchange of the Aventis ordinary shares tendered into the subsequent offering periods ended September 6, 2004, sanofi-aventis had acquired an aggregate of 791,317,811 Aventis ordinary shares representing 98.03% of the share capital and 98.09% of the voting rights of Aventis, based on 807,204,134 shares and 806,750,129 voting rights outstanding as of August 31, 2004. After giving effect to the offers, on a fully-diluted basis, sanofi-aventis held 92.44% of the share capital and 92.49% of the voting rights of Aventis. On October 14, 2004, each of the sanofi-aventis Board of Directors and the Aventis Supervisory Board met and voted to approve the agreement and plan of merger of Aventis with and into sanofi-aventis. On December 13 and 23, 2004, the respective extraordinary shareholder meetings of Aventis and sanofi-aventis adopted the agreement and plan of merger, and on December 31, 2004, Aventis merged with and into sanofi-aventis, with sanofi-aventis as the continuing company.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

From October 1 to December 10, 2004, pursuant to the German securities laws, sanofi-aventis conducted a mandatory offer for the outstanding shares of Hoechst AG not already indirectly acquired through the acquisition of Aventis, which held approximately 98.1% of Hoechst AG's share capital. The offer consideration was 51.23 per share, for a maximum aggregate transaction amount of approximately 550 million, including transaction

Table of Contents

costs. Upon registration of the squeeze-out resolution described below, those former Hoechst shareholders who tendered their shares in the mandatory offer will, as provided under the terms of the mandatory offer, receive an additional payment of 5.27 per tendered share as the difference between the offer price of 51.23 and the cash compensation of 56.50 resolved in relation to the squeeze-out. 583,515 Hoechst shares, representing approximately 0.1% of the share capital and voting rights of Hoechst AG, were tendered into the mandatory offer.

On November 4, 2004 Aventis confirmed its intention to conduct a squeeze-out of the remaining minority shareholders of Hoechst against adequate cash compensation. On December 20 and 21, 2004 at an Extraordinary Shareholder Meeting, the shareholders of Hoechst AG approved the squeeze-out resolution proposed by Aventis according to which the shares of the minority shareholders shall be transferred to Aventis (now sanofi-aventis) for cash compensation of 56.50 per share. The squeeze-out will become effective once the squeeze-out resolution is registered with the Commercial Register of Frankfurt.

A number of minority shareholders have filed lawsuits against the squeeze-out resolution before the District Court of Frankfurt (Landgericht). Hoechst AG has stated it regards these lawsuits as unfounded and has initiated so-called fast-track proceedings seeking to enable the timely registration of the squeeze-out resolution in the Commercial Register of Frankfurt.

In accordance with the Securities and Exchange Board of India takeover regulations, on August 11, 2004, sanofi-aventis announced that it intends to acquire up to 4,606,125 fully paid up equity shares of Aventis Pharma Limited India (a company that is 50.1% owned by Hoechst through its wholly owned subsidiary Aventis Pharma Holding GmbH) for a cash offer price of Rupee 792.20 (US\$17.30) per fully paid up equity share and aggregate consideration of Rupee 465 million (US\$79.7 million). The shares of Aventis Pharma Limited India are listed on the Stock Exchange, Mumbai and the National Stock Exchange of India Limited. The offer to the shareholders of Aventis Pharma Limited India is being made as a result of the offers pursuant to which sanofi-aventis acquired indirect control of Aventis Pharma Limited India. As of the date of this annual report, the offer documentation for the proposed acquisition is still under review by the competent Indian authorities.

We divested certain assets in connection with the acquisition, including two products, Fraxiparine[®] and Arixtra[®], that we sold in order to respond to potential demands from competition authorities in relation to the acquisition. Aventis also divested certain assets, including its product Campto[®]. See Item 5. Operating and Financial Review and Prospects Divestments .

B. Business Overview

Strategy

The acquisition of Aventis by sanofi-aventis created the leading pharmaceutical group in Europe in terms of sales and one of the leading pharmaceutical groups in the world with a strong direct presence in all major markets (IMS/GERS year end 2004). We believe that the enhanced scale, financial strength and research and development resources of the combined Group will allow us to better serve patients worldwide. The key elements of our strategy are to:

Capitalize on our direct presence in the United States, consolidate our leading position in Europe as well as enhance our solid and growing positions in Asia, Latin America and Africa. Prior to 2004 our strategy in the United States had been largely based on organic growth, with upgrades to our sales force and local infrastructure timed to match the progress of our product portfolio and product launches. As a consequence of the acquisition, our U.S. sales force now includes approximately 8,000 employees; and we

Edgar Filing: SANOFI-AVENTIS - Form 20-F

intend to use this powerful resource to build our leadership in the U.S. market. In Europe, where we have our historical Group foundations, we are the overall sales leader for the region, as well as in the major markets of France and Germany. Europe is also the home of a number of our key industrial and R&D sites. With regard to other countries, we intend to progressively strengthen our presence by developing our local subsidiaries and local sales forces when and where possible.

Increase the momentum of our products and strengthen our leading positions in major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic disorders, central nervous system, internal

Table of Contents

medicine and human vaccines. We plan to continue to develop our large portfolio of fast-growing drugs with six products having individual annual sales in excess of 1 billion during 2004 (Lovenox[®], Plavix[®], Allegra[®], Taxotere[®], Stilnox[®] and Eloxatine[®]) as well as to maximize the performance of our high potential products such as Lantus[®]. We intend to make the necessary investments in marketing and other resources to fully promote our high potential products which are in early stages of their life cycles and have significant remaining potential for sustained growth.

Capitalize on our research potential by selecting major projects and accelerating the development of the most promising compounds. We believe that with the magnitude of our R&D investments (third highest level of R&D spending in the industry), together with our reinforced scientific, technological and diverse industrial capabilities, we will be able to accelerate the efficiency of our R&D operations, which are expected to give us a solid foundation driving medium-and long-term growth. We intend to continue to focus our efforts on developing innovative products to satisfy unmet medical needs in our targeted therapeutic areas and to maintain our current high level of research and development spending as a percentage of revenues.

Continue to improve sales force productivity. Over the last few years, we have successfully improved the productivity of our sales force, reorganizing our affiliates in Europe to sharpen customer focus and achieving a critical mass in the United States to position the group among the leaders in productivity measured by the number of sales calls that result in a physician intending to change a prescription. We have continued to implement this strategy through the integration process over the past few months, and we believe that our focused structure gives us the opportunity to improve our profitability.

Continue to defend all our products worldwide, including some of our older products, which are of excellent quality and which play a vital role in balancing health-care system costs. Over time, we intend to maintain and consolidate our portfolio beyond our top 15 products through selective investments, remaining faithful to one of our fundamental principles: that there is no such thing as a small market or a small product.

Develop our presence in the generic activity in order to actively participate in making off-patent drugs more widely accessible, whether the princeps drug came from our own or from our competitor's research. In January 2005 we launched our worldwide generic trademark WINTHROP[®] Pharmaceuticals.

Respond in a concrete way to the major challenge of pharmaceutical needs in emerging countries through the establishment of a solidarity mission regarding access to medicine. Our goal is to provide this part of the world with products that are adapted in terms of price as well as therapeutic indications, and with our human vaccines, we plan to draw up a genuine program to meet the challenges of those populations.

Principal Products

Sanofi-aventis is organized around two main business activities: our pharmaceutical business, and our vaccines business; which is conducted through our wholly-owned subsidiary sanofi pasteur (formerly Aventis Pasteur).

In the description that follows in this Item 4, the following should be kept in mind:

A drug can be referred to either by its international non-proprietary name, or INN, or by its brand name, which is normally exclusive to the company that markets it. In most cases, our brand names, which may vary from country to country, are protected by trademark registrations. We have chosen in this annual report to generally refer to our products by the brand names that we use in France, except for Allegra[®] (sold in France as Telfast[®]), Tritace[®] (sold in France as Triatec[®]), and Amaryl[®] (sold in France as Amarel[®]).

Edgar Filing: SANOFI-AVENTIS - Form 20-F

For our pharmaceutical business, except where otherwise stated, all market share percentages and rankings are based on full-year 2004 sales figures from IMS Health MIDAS for all countries, except for France (GERS data).

For our human vaccines business, market shares and rankings are based on our own estimates. We are not aware of any industry or market reports that cover or address our role in the human vaccines market. Therefore we have assembled information based on various sources including industry contacts, statistical information we have collected and information published by competitors or otherwise.

Table of Contents

In this annual report, we present both our pro forma net sales from our products sold through alliances, and developed sales . See Item 5. Operating and Financial Review and Prospects, for the definition of developed sales .

Pharmaceutical Activity

Within our pharmaceutical business, we focus on six main therapeutic areas: cardiovascular, thrombosis, metabolic disorders, oncology, central nervous system and internal medicine.

Table of Contents**Top 15 products**

The following table sets forth the pro forma net sales of our top 15 products for the year ended December 31, 2004.

Top 15 products			
Therapeutic Area / Product Name	2004 Pro forma Net Sales	2004 Pro forma Developed Sales	Drug Category / Main Areas of Use
(millions of \$)			
Cardiovascular			
Aprovel® (irbesartan)	790	1,449	Angiotensin II receptor antagonist Hypertension
Tritace® (ramipril)	972		Angiotensin Converting Enzyme Inhibitor Hypertension Congestive heart failure after myocardial infarction
Thrombosis			
Lovenox® (enoxaparin sodium)	1,904		Low molecular weight heparin Deep vein thrombosis
Plavix® (clopidogrel)	1,694	4,108	Platelet adenosine disphosphate receptor antagonist Atherothrombosis
Metabolic disorders			
Lantus® (insulin glargine)	843		Long-acting analogue insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	684		Sulfonylurea Type 2 diabetes mellitus
Oncology			
Taxotere® (docetaxel)	1,436		Cytotoxic agent Breast cancer Non small cell lung cancer Prostate cancer
Eloxatine® (oxaliplatin)	1,220		Cytotoxic agent Colorectal cancer
Central Nervous System			
Stilnox® (zolpidem)	1,423	1,461	Hypnotic Sleep disorders
Copaxone® (glatiamer acetate)	742		Non-interferon immunomodulating agent Multiple sclerosis
Depakine® (sodium valproate)	303		Anti-epileptic Epilepsy
Internal Medicine			
<i>Respiratory/Allergy</i>			
Allegra® (fexofenadine)	1,502		Antihistaminic

Edgar Filing: SANOFI-AVENTIS - Form 20-F

		Allergic rhinitis
Nasacort® (triamcinolone acetonide)	287	Local corticosteroid
		Allergic rhinitis
<i>Urology</i>		
Xatral® (alfuzosin)	281	Uroselective alpha1-blocker
		Benign prostatic hypertrophy
<i>Osteoporosis</i>		
Actonel® (risedronate)	305	Biphosphonate
		Osteoporosis

Table of Contents

Cardiovascular

Within the cardiovascular market, hypertension remains the most prevalent disease. Hypertension is defined as blood pressure above the normal level and is one of the main causes of severe kidney, heart, brain, vessel and eye complications. Our principal products for the treatment of cardiovascular diseases are:

Aprovel®/Avapro®/Karvea®

Aprovel® (irbesartan) belongs to the fastest growing class of anti-hypertensives, angiotensin II receptor antagonists, and is indicated as a first-line treatment for hypertension. Angiotensin II receptor antagonists, which are highly effective, act by blocking the effect of angiotensin, the hormone responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. In addition to Aprovel®/Avapro®/Karvea®, we market CoAprovel®/Avalide®/Karvezide®, a fixed dose combination of irbesartan and hydrochlorothiazide (HCTZ), a diuretic that increases the excretion of water by the kidneys and provides an additive blood pressure lowering effect. These products achieve control of blood pressure in over 80% of patients with a very good safety profile.

Aprovel® was launched in 1997 and is now marketed in more than 80 countries, including the United States, through an alliance with Bristol-Myers Squibb, or BMS (under the brand name Avapro®). In Japan, where the product is licensed to BMS and Shionogi, an application for marketing authorization for the treatment of hypertension was submitted in October 2002, and the review is still ongoing.

Since 2002, Aprovel® is also approved for the treatment of diabetic nephropathy, in both Europe and the United States. These approvals were based on the results of the PRIME program, a clinical program that demonstrated that irbesartan protects type-2 diabetic hypertensive patients from the progression of renal impairment, at both early and more advanced stages of the disease. Following the announcement of the PRIME results, the American Diabetes Association (ADA) recommended the use of angiotensin receptor antagonists, such as Aprovel®, as a first-line treatment for renal disease in patients with type 2 diabetes.

In July 2004, as follow-up to an FDA request, we submitted an application for a pediatric indication for Aprovel® in the United States.

In 2004, we also launched the reduced mass coated tablet, a new and improved formulation of Aprovel®, in Europe.

The IMPROVE clinical trial was initiated in 2004 to demonstrate the end organ protective effects of Aprovel® in patients at high risk for cardiovascular events. Results of this 400-patient study are expected in 2006.

We are currently conducting two large-scale clinical programs as part of our life cycle management program for Aprovel® that will enroll a total of 14,100 patients and that we expect to complete in 2006/2007:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

I-PRESERVE evaluates the benefit of Aprove[®] in the treatment of diastolic heart failure, a specific but common form of heart failure. This 4,100-patient study was initiated in 2002, and recruitment is expected to be completed during the first half of 2005.

ACTIVE-I evaluates the efficacy of Aprove[®] combined with clopidogrel (the active ingredient in Plavix[®]), in preventing complications in patients suffering from atrial fibrillation. We began this clinical program in 2003, with enrolment for the 10,000-patient study ongoing. Results are expected in 2007.

Two important clinical efficacy trials for CoAprove[®] were completed in 2004:

The COSIMA trial in Europe demonstrates the superior anti-hypertensive lowering efficacy of CoAprove[®] versus the combination of valsartan with HCTZ. The results of this study were presented at the French Society of Hypertension meeting in December.

The INCLUSIVE trial, conducted in the United States, evaluated CoAprove[®] (under the brand name Avalide[®]) in uncontrolled hypertensive patients.

Table of Contents

Two trials in patients with severe and moderate hypertension have also been initiated in 2004 to evaluate CoAprovel[®] as a first-line treatment in this population.

In 2004, we submitted an application to the FDA to register the CoAprovel[®] 300 mg irbesartan / 25 mg HCTZ pharmaceutical form. This form was approved on March 15, 2005.

At the end of 2004, based on the total sales of Aprovel[®] and CoAprovel[®], we rank second in Europe (top 5 retail markets) and third in the United States among the angiotensin II receptor antagonists in the hypertension market. Our market share was 18.5% in the global market of angiotensin II receptor antagonists (total sales of Aprovel[®] and CoAprovel[®] in the EU top 5 retail markets and U.S. all channels).

Tritace[®]/Triatec[®]/Delix[®]/Altace[®]

Tritace[®] (ramipril) is an angiotensin converting enzyme (ACE) inhibitor for the treatment of hypertension, congestive heart failure after myocardial infarction and nephropathy. Its use has widely increased since the initial publication of the Heart Outcomes Prevention Evaluation (HOPE) study in 2000 showing it to be effective in reducing the incidence of stroke, heart attacks and cardiovascular death in high-risk patients. Tritace[®] is the only ACE inhibitor approved for the prevention of stroke, heart attack and cardiovascular death in people at high risk for cardiovascular events.

According to a report published in *Circulation* in September 2004, Tritace[®] significantly reduces the rate of fatal and non-fatal serious arrhythmic events. This sub-analysis of the HOPE study is the first to demonstrate that an ACE inhibitor can prevent arrhythmic events such as sudden death and cardiac arrest in patients at risk of atherosclerotic cardiovascular events.

A retrospective study published in July 2004 in the *Annals of Internal Medicine* evaluated whether all ACE inhibitors are associated with the same mortality in patients who have had a myocardial infarction. The results demonstrated that, among the different ACE inhibitors tested, Tritace[®] was associated with the lowest mortality rate, highlighting that there are structural, kinetic and pharmacological differences within the class, which can lead to important differences in clinical outcomes.

At the end of 2004, Tritace[®] is a market leader in Canada (rank: #1, market share 44.3%), France (ramipril rank: #2, market share 25.4%), Spain (rank: #1, market share 12.6% in the retail market) and Italy (ramipril rank: #2, market share: 23.0% in the retail market). Tritace[®] (under the brand name Delix[®]) continues to be still the market leader in Germany, with demand volumes stable, despite the end of market exclusivity in Germany in January 2004. The U.S. rights were sold to King Pharmaceuticals in 1998.

Thrombosis

Thrombosis occurs when a thrombus, or blood clot, forms inside a blood vessel. Left unchecked, a thrombus can eventually grow large enough to block the blood vessel, preventing blood and oxygen from reaching the organ being supplied. Our principal products for the treatment of thrombosis are:

Lovenox®/Clexane®

Lovenox® (enoxaparin sodium) is the most widely studied and used low molecular weight heparin (LMWH) in the world. It has been used to treat an estimated 151 million patients in 96 countries since it was first introduced in 1987 and is approved for more clinical indications than any other LMWH. Numerous clinical studies have demonstrated the product's benefits as an effective way to significantly reduce the incidence of deep vein thrombosis in a wide range of patient populations with a good safety profile, and also as an effective prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction when administered concomitantly with acetylsalicylic acid (ASA, the active ingredient in Aspirin®.)

The landmark, 10,027-patient SYNERGY study showed that Lovenox® is as effective as unfractionated heparin (UFH) in the treatment of high-risk patients with non-ST-elevation acute coronary syndromes undergoing an urgent invasive strategy. These data were presented on March 9, 2004, at the American College of Cardiology's Annual Scientific Session 2004.

The results of SYNERGY and a meta-analysis of 6 major trials (systematic overview) were published in the July 7, 2004 issue of the *Journal of the American Medical Association*. The results of this systematic overview of 21,946 randomized patients show that, overall, Lovenox® was significantly superior to UFH in preventing the composite of death or nonfatal myocardial infarction in non-ST-elevation acute coronary

Table of Contents

syndromes. The systematic overview also showed that major bleeding and transfusions at 7 days were similar in the two treatment groups.

The ExTRACT study utilizing Lovenox[®] as adjunctive therapy in patients with myocardial infarction receiving thrombolytic therapy is a global phase III trial with an expected enrolment of 21,000 patients. The trial is on track with more than 15,000 patients enrolled and enrolment expected to be completed in the third quarter of 2005.

In July 2004, the FDA approved our supplemental new drug application (sNDA) for Lovenox[®] that provided for revisions to the product labeling and CMC (chemistry manufacturing controls) outlining the 1,6-anhydro structural characteristic as a release specification.

Lovenox[®] is a market leader in all major countries, including the United States (rank: #1, market share 87.9%), France (rank: #1, market share 61.8%), Germany (rank: #1, market share 41.9%), Italy, Spain and the United Kingdom.

Plavix[®] / Iscover[®]

Plavix[®] (clopidogrel), a platelet adenosine diphosphate (ADP) receptor antagonist with a rapid onset of action that selectively inhibits platelet aggregation induced by ADP, is indicated for long-term prevention of atherothrombotic events in patients with a history of recent myocardial infarction, recent ischemic stroke or documented peripheral arterial disease. Plavix[®] is currently the only drug indicated for the secondary prevention of atherothrombosis regardless of the location of the arteries initially affected (heart, brain, lower limbs). This indication is supported by the results of the landmark CAPRIE trial, including almost 20,000 patients. CAPRIE demonstrated the superior efficacy of Plavix[®] to acetylsalicylic acid (ASA, the active ingredient in Aspirin[®]), with a comparable safety profile.

Plavix[®] was launched in 1998, and is now marketed in over 80 countries, including the United States, through our alliance with BMS. In Japan, where it is being developed in partnership with Daiichi, an NDA was submitted for marketing authorization in February 2004, and launch is expected in 2005.

Since 2002, Plavix[®] is also indicated for the treatment of ACS (non-Q-wave myocardial infarction and unstable angina pectoris) in combination with ASA following the impressive results of the CURE trial. This indication was rapidly incorporated into the guidelines of the American Heart Association, the American College of Cardiology, and the European Society of Cardiology. The CURE trial demonstrated that Plavix[®] provided significant early- and long-term benefits in patients presenting ACS. Plavix[®] reduced the relative risk of atherothrombotic events (myocardial infarction, stroke and death from cardiovascular cause) by 20% when added to standard therapy including ASA, with a 1% increase in the rate of major bleeding. With more than 12,000 patients enrolled, CURE is the largest clinical trial ever conducted with patients presenting unstable angina or non-Q-wave myocardial infarction.

Since 2003, at the request of the FDA, development of a pediatric indication for Plavix[®] in the United States – PICOLO study – is ongoing.

The benefits of Plavix[®] are supported by an extensive program of clinical studies:

The results of the CREDO clinical trial, announced in November 2002, confirmed the therapeutic value of Plavix® in the early- and long-term prevention of atherothrombotic events in patients having undergone coronary angioplasty, either with or without stenting. The CREDO trial, conducted in over 2,000 patients, demonstrated the efficacy of Plavix® by reducing the relative risk of atherothrombotic events by 27% after one year.

The MATCH trial results released in March 2004 demonstrated that ASA did not show additional clinical value (benefit/risk ratio) in specific patients who have recently experienced a stroke or transient ischemic attack when added to Plavix® and other standard therapies.

The CHARISMA landmark trial completed its enrollment of over 15,600 patients in 2003. CHARISMA aims to demonstrate the clinical value of Plavix® in patients at high risk of future cardiovascular events. Patients included in CHARISMA present a combination of major cardiovascular risk factors and/or previous ischemic events (e.g., myocardial infarction, stroke, transient ischemic attack, etc.). The end of follow-up for this event-driven trial is expected for late 2005 and the first announcement of the results for 2006.

Table of Contents

On March 9, 2005, the results of two major clinical trials were released at the 54th Annual Scientific Session of the American College of Cardiology. These studies demonstrated that Plavix[®], in addition to standard therapy, improved coronary perfusion and reduced mortality in acute heart attack.

The CLARITY trial, conducted in nearly 3,500 patients, demonstrated that Plavix[®], added to standard therapy including fibrinolytics and ASA, reduced the odds of acute myocardial infarction patients having another occluded artery or a second heart attack or death after 1 week of hospitalization, as well as the odds of clinical events (cardiovascular death, recurrent myocardial infarction, certain recurrent ischemia) at 30 days.

The COMMIT trial, which enrolled nearly 46,000 patients, demonstrated that Plavix[®], added to standard therapy including ASA, reduced mortality in acute myocardial infarction patients at day 28 in an in-hospital setting.

In both trials, the rates of major bleeding and intracranial hemorrhage were similar in both the Plavix[®] and placebo groups, underlining the favorable risk/benefit profile of Plavix[®].

Other major ongoing clinical studies that are designed to support the long-term value of Plavix[®] by providing complementary clinical data include:

CASPAR, which assesses the clinical value of Plavix[®] in patients with peripheral arterial disease who have undergone peripheral bypass surgery, is planned to include 1,400 patients.

ACTIVE, which assesses the value of Plavix[®] in patients with atrial fibrillation for the prophylaxis of cardio-embolic events, is expected to include 14,000 patients and, with results expected in 2007 or 2008.

In 2003, one of the largest disease registries was initiated to evaluate patients at risk of atherothrombosis. This registry called REACH – Reduction of Atherothrombosis for Continued Health – included 63,000 patients in more than 43 countries. Preliminary data from this registry indicate that although there are substantial differences in the incidence of risk factors a consistent pattern of underachievement of therapeutic goals is nonetheless evident across patient types and geographic regions. Further analysis of this population will follow.

The extensive clinical program for Plavix[®], including all completed, ongoing and planned studies, is one of the largest of its kind and will enroll more than 100,000 patients. In addition, over 41 million patients worldwide are estimated to have been treated with Plavix[®] since its launch, providing significant safety and efficacy experience with this product.

Plavix is the leader in the European and U.S. markets for anti-platelet agents with Plavix[®].

Metabolic Disorders

Lantus[®]

Lantus® (insulin glargine) is a long-acting analogue insulin, indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes mellitus who require basal insulin for the control of hyperglycemia, and for adult and pediatric patients with type 1 diabetes mellitus. The characteristics of Lantus® are a consistent slow, prolonged absorption and a relatively stable concentration/time profile over 24 hours.

The simplicity of the once-daily insulin injection regimen can facilitate a more timely and effective insulin use in routine medical practice, improving achievement of recommended standards of diabetes care.

An important number of studies were published in late 2003 and 2004. A selection of studies is presented here:

One major study was published in November 2003 in *Diabetes Care* evaluating 756 type 2 diabetic patients. The Treat-to-Target 24-week trial showed that significantly more type 2 diabetic patients treated with Lantus® achieved a target goal of A1C under or equal to 7%, (a measure indicating a good control of long-term blood sugar level), without having an episode of nocturnal hypoglycemia.

Another study published in *Diabetic Medicine* in 2004 conducted with 121 type 1 diabetic patients showed that a one-year basal bolus regimen using Lantus® as the basal insulin resulted in a significant improvement in A1C level and limited the frequency of hypoglycemia more than a basal bolus regimen using Neutral Protamin Hagedorn (NPH) four times a day as the basal insulin, which is the conventional treatment.

Table of Contents

In addition, two major studies were presented in 2004 and published at the American Diabetes Association (ADA) 64th Annual Scientific Sessions and at the 40th Annual Meeting of the European Association for the Study of Diabetes (EASD):

The LAPTOP 24-week study demonstrated that when oral anti-diabetic drugs (OADs) alone no longer control hyperglycemia in insulin-naïve type 2 diabetes patients, adding once-daily Lantus[®] while continuing OADs restores glycemic control more effectively and with less risk of hypoglycemia and lower insulin requirements than the conventional practice of switching to twice-daily premixed insulin without OADs. The A1C decline from baseline was greater with Lantus[®] plus OADs than with the conventional therapy and more subjects reached the target of A1C under 7% without documented nocturnal hypoglycemia. The full paper was published in *Diabetes Care* in February 2005.

The LANMET 9-month study showed that, in insulin-naïve type 2 diabetic patients, good glycemic control can be achieved using Lantus[®] plus metformin, an OAD, with infrequent visits to a physician. Using modem-assisted glucose monitoring, patients can successfully self-monitor and self-adjust basal insulin dosing. Use of Lantus[®] was associated with better pre- and post-dinner glycemic control, and resulted in significantly less hypoglycemia than NPH. Symptomatic hypoglycemia was 44% more frequent with NPH than with Lantus[®].

In August 2004, the FDA approved OptiClik[®], a new reusable pen for injecting Lantus[®] for people with type 1 and type 2 diabetes. The Lantus[®] cartridge for OptiClik[®] was also approved by the European Commission in August and by the Japanese regulatory authorities in September 2004. The OptiClik[®] pen is expected to provide people with diabetes with a new and easy-to-use delivery option.

Lantus[®] was first launched in 2000 in Germany and is now available in over 70 countries throughout the world. In 2004, Lantus[®] was launched in over 30 countries including Spain, Belgium, Denmark, Greece, Turkey, Brazil, Mexico and China.

The largest insulin market after the United States is Germany followed by Japan. At year end 2004, Lantus[®] was the top-selling insulin brand worldwide. The top three markets for Lantus[®] are the United States (rank: #1, market share: 23.7%), Germany (rank: #1, market share: 13.5%) and the United Kingdom (rank: #2, market share: 17.5%).

Amaryl[®]/Amarel[®]/Solosa[®]

Amaryl[®] (glimepiride) is a once-daily sulfonylurea for the oral treatment of type 2 diabetes as an adjunct to diet and exercise. Studies also prove the effective combination of Amaryl[®] with Lantus[®], if oral treatment alone does not provide tight diabetes control. Amaryl[®] reduces the body's blood sugar level by a dual mode of action: helping the body to produce more insulin both at mealtime and during the interprandial periods and decreasing insulin resistance. Studies demonstrate that a very good level of control can be reached with a low risk of hypoglycemia. Amaryl[®] was first launched in 1995 and has been approved in about 100 countries worldwide. The top three markets for Amaryl[®] are the United States (rank: #4, market share 5.4%), Japan (rank: #2, market share 11.2%) and Germany (rank: #1, market share 23.1%).

Oncology

Sanofi-aventis is a leading group in the oncology field, primarily in chemotherapy with two major agents: Taxotere[®] and Eloxatine[®]. Our principal products in oncology are:

Taxotere®

Taxotere® (docetaxel) is a taxane derivative that acts by disrupting cell mitosis and is the only cytotoxic agent currently approved in three major types of cancer: first-line treatment of non small cell lung cancer (NSCLC), treatment of metastatic and early breast cancer and androgen-independent (hormone-refractory) metastatic prostate cancer. First launched in 1995 and marketed in over 86 countries, Taxotere® continues to be extensively studied in breast cancer as well as prostate, head and neck, lung, and gastric cancers.

Table of Contents

Taxotere[®] continued to provide benefits to cancer patients in 2004. At two plenary sessions at the 2004 Annual Meeting of the American Society of Clinical Oncology (ASCO), the premier international oncology scientific meeting, studies evaluating Taxotere[®] demonstrated the first improvement in survival in men with hormone-refractory metastatic prostate cancer. Based on the results of these studies, Taxotere[®] was approved by the FDA in May 2004 for use in combination with prednisone as a treatment for men with hormone-refractory metastatic prostate cancer. EU approval of the same indication was granted in November 2004.

In 2004, Taxotere[®] also received approval from the FDA in the United States (August) and the EMEA in Europe (December) for the adjuvant (post-surgery) treatment of patients with operable node-positive breast cancer. The efficacy of Taxotere[®] in this indication was demonstrated in two large phase III studies (TAX 316 (BCIRG001) and PACS01). The results of PACS01 study, presented at the 2004 San Antonio Breast Cancer Symposium, showed a 91% 5-year survival rate for women following a sequential Taxotere[®] regimen.

In late 2004, the combination treatment Taxotere[®]/trastuzumab was also approved in Europe for the treatment of patients with metastatic breast cancer whose tumors over-express the Her2 gene.

In the first head-to-head phase III comparison with paclitaxel (TAX 311 study) in metastatic (advanced disease) breast cancer, results showed that Taxotere[®] significantly improved survival and time to disease progression over paclitaxel, with a predictable and manageable safety profile.

Also at ASCO 2004, the final results of a phase III trial, in which Taxotere[®] was added to standard therapy prior to radiation in head and neck cancer; was reported. These results showed that adding Taxotere[®] leads to significantly higher response rates, improved overall survival and lower levels of toxicity.

The final results of the study evaluating Taxotere[®] in gastric cancer are expected in 2005.

The top 3 countries contributing to our sales of Taxotere[®] are respectively the United States, France and Germany (based on pro forma net sales). The reimbursement system applied in the United States up until end of 2004 favored generics such as paclitaxel over Taxotere[®] when several therapeutic possibilities existed for the same indication. The revised system no longer favors generics over Taxotere[®], allowing prescriptions of the product most adapted to the patient.

Eloxatine[®]

Eloxatine[®] (oxaliplatin) is an innovative platinum agent, and is currently the only agent indicated both for the treatment of metastatic colorectal cancer and for adjuvant treatment of colon cancer.

In the United States, France, Germany, Italy, Spain, the United Kingdom and Japan more than 500,000 people are diagnosed every year for the first time with colorectal cancer. Colorectal cancer is the second cause of death from cancer in the United States. Colorectal cancer with distant metastases (named stage IV) makes up around 30% of all new colorectal cancer diagnoses per year. When diagnosed at an early stage, chances of cure with surgery increase dramatically. Chemotherapy is used as an adjuvant therapy to surgery in order to prevent recurrences.

The development of Eloxatine[®] for the treatment of metastatic colorectal cancer has led to major progresses. First, median survival has been prolonged to 20 months when Eloxatine[®] is used as a first-line treatment in combination with 5-fluorouracil (or 5-FU) and leucovorin (LV) (the FOLFOX regimen). Second, thanks to its demonstrated ability to reduce the size and number of liver metastases, Eloxatine[®] has made the complete surgical removal of hepatic metastases and has given the hope of a potential cure in a significant proportion of patients with initially unresectable liver metastases. Therefore, due to its consistently high and sustained efficacy in treating metastatic colorectal cancer, the FOLFOX regimen is a mainstay treatment of metastatic colorectal cancer in the United States, Europe and certain countries in the Asia-Pacific region.

Eloxatine[®] is now recognized as a cornerstone chemotherapy to which new biological agents (eg. monoclonal antibodies or small molecules) could be combined, with the hope to further increase the survival rate. Thus, in January 2005, results from an interim analysis of a U.S. cooperative group study (ECOG 3200) were presented at ASCO Gastrointestinal Cancers Symposium in the United States. These results have shown that patients receiving bevacizumab in addition to FOLFOX had a 26% reduction in the risk of death, compared to patients receiving FOLFOX alone.

Table of Contents

Eloxatine[®] has also been developed for adjuvant treatment of colon cancer. Eloxatine[®] was the first anticancer agent to allow a significant improvement of the adjuvant treatment of colon cancer in a decade. Based on the results of the MOSAIC clinical trial, which studied the efficacy of Eloxatine[®] as an adjuvant treatment in over 2,200 patients, approval for adjuvant treatment was respectively granted by the European agency and the FDA on September 12, 2004 and on November 4, 2004. MOSAIC showed that the addition of Eloxatine[®] to the previous post-surgery reference chemotherapy of 5-FU/LV for colon cancer reduces the risk of recurrence by 23% when compared to the reference treatment alone. FOLFOX is now the standard treatment for stage III colon cancer patients who have undergone complete resection of the primary tumor.

Its activity in colorectal cancer has also encouraged specialists to explore the value of Eloxatine[®] in the treatment of other tumors, particularly gastrointestinal tumors, such as pancreatic cancer or gastric cancer, as well as lung, ovarian, breast and certain hematological cancers.

A new liquid formulation (Eloxatine[®] Injection) was approved on January 31, 2005 by the FDA. Eloxatine[®] Injection offers additional benefits and convenience to physicians and nurses since it involves fewer steps in the administration of Eloxatine[®].

Eloxatine[®] is in-licensed from Debiopharm and is marketed in nearly 70 countries worldwide. The top 3 countries contributing to our sales of Eloxatine[®] are respectively the United States, France and Germany (based on pro forma net sales).

Central Nervous System

We have long-standing expertise in the Central Nervous System therapeutic area. Our principal products in this area are :

Stilnox[®]/Ambien[®]/Myslee[®]

Stilnox[®] (zolpidem) is the worldwide hypnotic leader and is indicated in the short-term treatment of insomnia. Stilnox[®] is both chemically and pharmacologically distinct from benzodiazepines, and is distinguished by its selective binding to receptors that are presumed to mediate hypnotic activity. Due to this characteristic, Stilnox[®] rapidly induces sleep that is qualitatively close to natural sleep and devoid of certain side effects that are characteristic of the benzodiazepine class as a whole. Its action lasts for a minimum of six hours, and it is generally well tolerated, allowing the patient to awake with a reduced risk of impaired attention, decreased alertness or memory lapses throughout the day. The risk of dependence is minimal when Stilnox[®] is used at the recommended dosage and duration of use. Stilnox[®] is currently the only hypnotic demonstrated to be suitable for as needed use based on an extensive program of eight clinical trials, which together enrolled over 6,000 patients. This mode of administration avoids the systematic intake of a hypnotic by patients who suffer only occasionally from insomnia.

We believe that Stilnox[®] is also one of the most studied hypnotics in the world to date, as data on its efficacy and safety have been generated from 160 clinical trials including 80,000 patients worldwide.

To further improve the efficacy of Stilnox[®] regarding sleep maintenance without inducing next-day residual effects, we have developed a controlled release formulation of zolpidem. Two 3-week placebo-controlled studies, ZOLADULT and ZOLELDERLY, conducted in sleep laboratories assessed the efficacy and safety of the controlled release formulation of zolpidem in the treatment of patients experiencing insomnia.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

The studies showed that controlled release formulation of zolpidem improved sleep maintenance, sleep duration and the ability to fall asleep compared to placebo. Based on these results, we filed an application for the approval of the controlled release formulation of zolpidem in the United States in June 2004 and in certain countries in Europe in November 2004. A clinical development program has also been initiated in Japan. On April 11, 2005, we announced that we received an approvable letter from the FDA for Ambien CR (zolpidem tartrate extended release) for the treatment of insomnia.

Stilnox[®] was first launched in 1988 in France and is marketed today in over 100 countries. In Japan, although launched only in December 2000, Stilnox[®] has become the leading hypnotic on the market within 3 years of launch. It is sold under the brand name Myslee[®] through our joint venture with Fujisawa. Our top three markets for Stilnox[®] are the United States (rank: #1, market share 89.0%), Japan (rank: #1, market share 24.0%) and France, where generics became available in January 2004 (rank: #1, market share 37.7%).

Table of Contents

Copaxone®

Copaxone® (glatiramer acetate) is an immunomodulating agent indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis (MS). This disease-modifying drug is characterized by an original and specific mode of action on MS. Clinical studies have shown that Copaxone® is more effective than placebo at two years, but also that it has a clinical efficacy over ten years both in reducing relapses and progression of disability. A significant effect on lesions has also been confirmed by nuclear magnetic resonance imaging (MRI).

Copaxone® was first launched in 1997 in the United States and between 2000 and 2002 in Europe. It is in-licensed from Teva and marketed via our alliance with Teva. Additional details on this alliance can be found in [Alliances](#) below.

In Europe in 2004, in cooperation with our alliance partner Teva, we launched a new formulation of the product – a pre-filled syringe – in order to improve product delivery and patient comfort.

More than 80,000 patients worldwide are treated with Copaxone®. The three leading countries for its use are the United States (rank: #2, market share 27.9%), Germany (rank: #4, market share 18.6%) and Canada (rank: #2, market share 23.7%).

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for over 37 years. Numerous clinical trials, as well as long years of experience have shown that it is effective for all types of epileptic seizures and epileptic syndromes, and is generally well tolerated. Consequently, Depakine® remains a reference treatment for epilepsy worldwide. Furthermore, in contrast to findings sometimes reported with other anti-epileptic agents, Depakine® does not induce paradoxical aggravation of seizures.

We produce a wide range of formulations of Depakine® (syrup, oral solution, injection, entero-coated tablets and Chrono, a sustained release formulation in tablets) permitting its adaptation to most types of patients. Depakine® Chronosphere®, a new innovative, tasteless, sustained release formulation of Depakine® packaged in stick packs, facilitating its use by children (first Depakine® sustained release form for children), elderly and adults with difficulties swallowing, has been approved in several European countries, and was commercialized for the first time in Austria in October 2004. We plan to commercialize this new formulation gradually over the next few years as we register the product in additional countries.

Depakine® is marketed in over 100 countries, including the United States where it is licensed to Abbott. In 2004, we received marketing approval in several European countries for Depakine® Chrono and Chronosphere® for use in the treatment of bipolar disorder.

Internal Medicine

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Our principal products in this therapeutic area are in the fields of respiratory/allergy, urology and osteoporosis.

Respiratory/Allergy

Allegra®/Telfast®

Allegra® (fexofenadine HCl) is an effective, long-lasting (12- and 24-hour dosing) and powerful non-sedating prescription antihistamine for the treatment of seasonal allergic rhinitis (hay fever) and the skin condition chronic idiopathic urticaria (hives). It offers patients powerful relief from allergy symptoms without causing drowsiness. Our top three markets for Allegra® are the United States (rank: #1, market share 38.9%), Japan (rank: #2, market share 17.7%), and Australia (rank: #1, market share 42.6%).

We also offer Allegra-D® 12 Hour, an antihistamine/decongestant combination product with an extended-release decongestant for effective non-drowsy relief of seasonal allergy symptoms including nasal congestion. In October 2004, we received approval from the FDA for Allegra-D® 24 Hour, a once-daily

Table of Contents

formulation of an antihistamine/decongestant combination.

In December 2004, we filed a U.S. new drug application (NDA) for a 180 mg once-daily dose for adult chronic idiopathic urticaria. We made an NDA submission for a pediatric indication in Japan in February 2004 and we are developing two new pediatric formulations - 30 mg orally disintegrating tablets and 6 mg/ml oral suspension - with the intention of filing U.S. NDAs for both in 2005.

The top three markets for Allegra-D® 12 Hour are the United States (rank: #1, market share 49.0%), Brazil (rank: #4, market share 12.5%), and Mexico (rank: #8, market share: 2.4%).

In May 2001, a majority of the members of a joint Advisory Committee of the FDA recommended that Allegra® and two competing drugs be switched from prescription to over-the-counter (OTC) status. Since that date, the manufacturer of one of the two competing drugs has voluntarily switched its drug to OTC status. The FDA has not acted publicly on the Advisory Committee's recommendation with respect to Allegra® and it is not possible to predict what action, if any, the FDA might take in response to the Advisory Committee recommendation.

Nasacort®

Nasacort® (triamcinolone acetonide) AQ Spray is an unscented, water-based metered-dose pump spray formulation unit containing a microcrystalline suspension of triamcinolone acetonide in an aqueous medium. It is indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children six years of age and older.

In April 2004, we received approval from the FDA for Nasacort® HFA Nasal Aerosol, the first intranasal corticosteroid dry-aerosol formulation approved in the United States that contains hydrofluoroalkane (HFA) rather than chlorofluorocarbons (CFCs).

Nasacort® HFA Nasal Aerosol will provide physicians and patients with a new option for those seeking a dry-aerosol formulation for the management of nasal allergy symptoms. It replaces Nasacort® Nasal Inhaler, which was taken off the market in July 2003 to comply with Environmental Protection Agency (EPA) and FDA requirements intended to protect the ozone layer and that required the removal of nasal inhalers containing CFCs from the U.S. market.

Our leading markets for Nasacort® AQ Spray are the United States (rank: #3, market share 14.4%), France (rank: #2, market share 19.3%) and Canada (rank: #3, market share 9.8%).

Urology

Xatral®

Xatral® (alfuzosin) belongs to the alpha1-blocker class, and was the first product of the class to be indicated uniquely and specifically for the treatment of the symptoms of benign prostatic hyperplasia (BPH), as well as the first marketed product capable of acting selectively on the urinary system. Due to this clinical uroselectivity, Xatral® is immediately effective, with no need for dose titration, and shows good tolerability, particularly cardiovascular. Active from the first dose, it provides rapid and lasting symptom relief; improving patient quality of life. Xatral® has demonstrated a good safety profile, with very marginal blood pressure changes even in elderly or hypertensive patients. Cardiovascular safety results from combination of Xatral® with a PDE5 inhibitor will be released in 2005 further demonstrating Xatral®'s good cardiovascular safety profile.

Besides this symptomatic action, a large clinical program has been launched to document the use of Xatral® for the management and prevention of the most severe complication of BPH: acute urinary retention (AUR).

The results of the first trial (ALFAUR study) showed that Xatral® doubles the probability of restored capacity to urinate normally after an episode of AUR in conjunction with catheter insertion and reduces the need for BPH surgery up to 6 months after. These are the first published results that demonstrate the capacity of Xatral® to manage and prevent acute urine retention. Since 2003, we have obtained authorizations of this extension of the indication in 41 countries worldwide including 16 European countries.

Table of Contents

BPH is also widely known to be linked with various degrees of sexual dysfunction. The results of another international trial with over 800 patients have shown that Xatral® preserves sexual function, particularly ejaculatory function, in patients suffering from BPH.

Since its launch in 1988 in France, we have constantly worked on optimizing the formulation of Xatral®. The new once-daily formulation of Xatral® (branded Uroxatral® in the United States) has now been registered in over 90 countries and is marketed worldwide except in Australia and Japan. Our leading markets for Xatral® are France (rank: #1, market share: 24.6%), Italy (rank: #3, market share: 12.2%) and the United States (rank: #4, market share: 3.1%). We also began Phase IIb clinical trials of the once-a-day formulation of Xatral® for the treatment of BPH in Japan.

Osteoporosis

Actonel®/Optinate®/Acrel®

Actonel® (risedronate sodium) is a bisphosphonate that helps prevent bone loss by inhibiting bone resorption. Actonel® 35 mg once-a-week and Actonel® 5 mg daily are indicated for the prevention and treatment of postmenopausal osteoporosis and Actonel® 5 mg daily for the treatment of glucocorticoid induced osteoporosis either initiating or continuing systemic glucocorticoid treatment (> 7.5 mg per day of prednisone or equivalent) for chronic diseases. Actonel® 30 mg is also approved for the treatment of Paget's disease, a rare bone disorder. Actonel® is the only osteoporosis treatment that reduces the risk of vertebral fracture in just six months (Roux and al.). According to the results of a long-term clinical trial, Actonel® helped patients maintain a low incidence of new vertebral fractures over seven years of treatment. Actonel® also differentiates itself by its gastrointestinal tolerability demonstrated in large pivotal clinical trials.

Recent data shows that Actonel® is effective in preventing bone loss and preserving trabecular architecture within one year of treatment, an effect that may contribute to the early reduction in risk of vertebral fracture observed with Actonel®.

Actonel® is in-licensed from Procter & Gamble Pharmaceuticals and is co-marketed by sanofi-aventis and Procter & Gamble Pharmaceuticals through the *Alliance for Better Bone Health*. In Japan, Actonel® is marketed by sanofi-aventis under a license from Ajinomoto. Actonel® was first launched in 1998 in the United States and is currently approved in 92 countries. In 2004, Actonel® reached a market share of 21.6% in the global market. The top four markets for Actonel® are the United States, France, Germany and Canada.

Other pharmaceutical products

In addition to our top 15 products, the rest of our pharmaceutical portfolio includes a wide range of prescription drugs, over-the-counter products and generics. This part of the portfolio represents a significant part (39.5%) of our pharmaceutical activity, provides a solid foundation for our global sales and supports the growth of our top 15 products. Our goal is to renew the growth of this part of the portfolio through innovative approaches to promotion and resource allocation that will ensure its continued profitability.

Our other pharmaceutical products cover a large number of therapeutic areas and allow us to satisfy a large portion of the medical needs of both patients and healthcare professionals. Among others, we have a number of products in the fields of antibiotics, cardiovascular, pain management

Edgar Filing: SANOFI-AVENTIS - Form 20-F

and gastrointestinal drugs. We have always been closely involved in antibiotic research and can thus offer a broad range of solutions adapted to different medical needs. Our antibiotics include a wide variety of drugs such as Ketek[®], our most recently launched antibiotic (2004 in the United States), Claforan[®], Oflocet[®]/Tarivid[®], Pyostacine[®], Rovamycine[®] and Targocid[®]. We are also active in the battle against tuberculosis, a major public health problem in certain emerging countries, with the antibiotics Rifadine[®], Rifater[®] and Rifinah[®]. In the cardiovascular field, we have a wide range of products such as Lasilix[®] (diuretic), Cordarone[®] (antiarrhythmic) and Tildiem[®] (calcium antagonist). For treating pain, our portfolio of analgesics offers a level I treatment with Aspégic[®] and Doliprane[®], and level II treatment with Propofan[®] and Di-Antalvic[®]. In terms of gastrointestinal drugs, our portfolio includes a number of products that are sold over-the-counter in particular Maalox[®], Essentiale[®] and Enterogermina[®], which are among our top five OTC products in terms of pro forma net sales.

Table of Contents

Sanofi-aventis has also specifically decided to participate in the generics market. We currently have a generics business in seven countries: the United Kingdom, France, Portugal, Colombia, Germany, the Czech Republic and South Africa where operations are only just beginning. We plan to enter in some additional countries by the end of 2006. Since January 2005, our worldwide generics business is conducted under the WINTHROP® Pharmaceuticals name.

Human vaccines activity

Our subsidiary sanofi pasteur is a fully integrated vaccine business offering the broadest range of vaccines in the industry. In 2004, sanofi pasteur immunized over 500 million people against 20 serious diseases and generated pro forma net sales of 1.6 billion.

Based on our estimates, sanofi pasteur is a world leader in the vaccine industry and holds a leading position in most countries. In the United States and Canada, which account for approximately 50% of the worldwide vaccines market, sanofi pasteur is the market leader with a 28% market share. In 2004, North America accounted for 50% of sanofi pasteur's global activity (defined as the sum of our pro forma sales and 100% of the sales of Sanofi Pasteur MSD, but excluding our sales to Sanofi Pasteur MSD).

In Europe, our vaccine business is conducted through Sanofi Pasteur MSD, a 50-50 joint venture between sanofi pasteur and Merck & Co, which provides vaccines to 19 countries. With a 36% market share in 2003, Sanofi Pasteur MSD was the market leader in Europe, particularly in France, the UK and Germany. In 2004, sales of Sanofi Pasteur MSD, which is accounted for using the equity method, were 651 million, which represents 30% of sanofi pasteur's global activity.

Sanofi pasteur has established a leading position in Latin America, has been expanding its presence in Asia, particularly in China and Japan, and is very active in the supply of donated vaccines through organizations, such as UNICEF. The remainder of sales is generated in emerging countries.

Main Areas

Pediatric combination vaccines: The components of these vaccines vary because of diverse immunization schedules throughout the world. Protecting against up to six diseases, this group of products is anchored by acellular pertussis components in general and by the trivalent vaccine DAPTACEL® in particular. DAPTACEL®, protects against pertussis diphtheria and tetanus, and was launched in the United States in 2002 and has become a strong sales contributor due to its synergy with immunization schedules. ActHIB®, for the prevention of *Haemophilus influenzae* type b, is also an important growth driver within the pediatric product line. Pentacel® is a new vaccine against five diseases (pertussis, diphtheria, tetanus, polio and *Haemophilus influenzae* type b) that is approved in nine countries and has been a standard of preventive care in Canada since its launch in 1997. Pediacel®, another acellular pertussis-based pentavalent vaccine, was launched in the UK in 2004 and will be launched in several other EU countries in 2005.

Influenza: With a 37% share of the 1.4 billion influenza vaccine market, sanofi pasteur is the world leader in the production and marketing of influenza vaccines. Since 1995, sales of the influenza vaccines Fluzone® and Vaxigrip®/Mutagrip® have nearly tripled and production capacity was recently increased to 165 million doses to better meet demand. We expect demand for influenza vaccines to grow strongly within the next decade in the United States alone, due to increasingly broad government immunization recommendations. Strong growth has been experienced in China and Korea and this trend is expected to continue over the next several years. The Latin American market has experienced solid growth

Edgar Filing: SANOFI-AVENTIS - Form 20-F

and, in 2004, Fluzone® and Vaxigrip® achieved a 78% market share in Mexico. In April 2005, sanofi pasteur and the U.S. Health and Human Services Department (HHS) entered into a five-year agreement to speed the production process for new cell culture influenza vaccines in the U.S. and to design a U.S.-based cell-culture vaccine manufacturing facility.

Polio: Sanofi pasteur is the world's leading manufacturer of oral and inactivated polio vaccines (IPV), IPO® and Imovax® Polio. We expect the use of IPV vaccines to increase as the goal of global polio eradication is nearly reached with only six countries in the world that are still polio-endemic. As a result, sanofi pasteur is expanding its production capacity to meet this growing demand. The worldwide polio eradication initiative of the World Health Organization and UNICEF has positioned sanofi pasteur as a global preferred partner with both oral polio vaccine and IPV vaccines. In March 2005, sanofi pasteur's new polio vaccine (Monovalent Oral Polio Vaccine 1) was licensed by the French regulatory authorities (AFSSAPS). This new vaccine will first be used in Egypt as part of a new World Health Organization strategy to end polio transmission by the end of 2005.

Table of Contents

Adult and adolescent boosters: The incidence of pertussis (whooping cough) is on the rise globally, affecting both children and adults. Its resurgence, combined with an increased awareness of the dangers of vaccine-preventable diseases in general have led to higher sales of this product group in recent years. Sanofi pasteur submitted Adacel, which will be the first trivalent booster against diphtheria, tetanus and pertussis, for U.S. FDA approval in 2004 (see Vaccines Research and Development below). Adacel became the standard of care in Canada in 2004 where the majority of provinces provide routine adolescent immunization. This product will play an important role in efforts to better control pertussis by not only preventing the disease in adolescents and adults, but also by breaking the cycle of transmission impacting infants too young to be immunized or only partially vaccinated.

Meningitis: sanofi pasteur is the only company to offer a quadrivalent vaccine against this meningococcal meningitis, arguably the deadliest form of meningitis, in the United States. The polysaccharide vaccine Menomune[®] has grown rapidly particularly due to use among college students and military personnel. Menactra[®], a conjugate vaccine that is expected to offer a longer-lasting immune response, was approved by the FDA, in January 2005 for use in adolescents and adults aged 11-55 years. Meningitis vaccines are expected to become a significant growth contributor due to their anticipated future use in adolescents and infants under age 2. On March 17, 2005, sanofi pasteur filed a supplemental application with the FDA to amend Menactra[®] s license to include children aged 2 to 10 years.

Travel vaccines: Offering the widest range of vaccines in the industry, sanofi pasteur s product offering includes vaccines for typhoid, rabies, yellow fever, Japanese encephalitis, and cholera.

Research and Development

With a budget of approximately 4 billion for 2005, our Research and Development activity will support the growth of our company, bring to the market innovative and high potential drugs, and develop and strengthen our portfolio.

We have two Research and Development organizations: one for our pharmaceutical activity (Scientific and Medical Affairs) and the other dedicated to our human vaccines activity, sanofi pasteur.

Pharmaceutical Research and Development

In 2004, the formation and integration of sanofi-aventis Scientific and Medical Affairs opened for our Group a powerful basis for growth.

The objective of sanofi-aventis Scientific and Medical Affairs is to discover, develop, register and launch highly innovative compounds answering major unmet medical needs worldwide. For this, sanofi-aventis Scientific and Medical Affairs rely on their global structure, on their Discovery and Development organizations, and on a rich, innovative and balanced portfolio.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Sanofi-aventis Scientific and Medical Affairs are a global force of 16,000 people working in 24 sites, in 8 countries and 3 continents (in addition to the R&D sites, Clinical Research Units have been created in 23 countries).

Global and focused organizations: Discovery and Development

While Discovery and Development have specific objectives and organizational approaches, they also share the same global goal to bring innovative drugs to the market and work towards this goal. Both Discovery and Development have focused their activities in our major therapeutic areas:

Cardiovascular;

Thrombosis;

Metabolic Disorders;

Oncology;

Central Nervous System; and

Internal Medicine.

Table of Contents

Discovery Research

The objective of Discovery Research is to provide Development Research with a pipeline of high quality, innovative drugs. In this context, its principal goals established within the framework of the new sanofi-aventis Discovery perimeter are:

to discover and propose for Development each year promising molecules (new molecular entities or NCEs) that have the potential to fulfill unmet medical needs or provide improved treatments for patients; and

to provide scientific support for compounds under development or which are already commercialized (e.g. line extension, mechanism of action, biomarkers).

To this end, the therapeutic and scientific expertise of our scientists is leveraged with 3,000 multinational researchers currently located in 17 Pharmaceutical Research centers across Europe and the United States. Our aim is to capitalize upon the unique skill of our scientists in order to conduct high quality research that will fulfill the expectations of our top management, shareholders and, above all, of patients who are in need of novel drugs to improve their quality of life.

Discovery Research aims to identify and select the most pertinent targets for innovative drugs and subsequently to exploit both biological and chemical expertise to discover and propose new candidate molecules for Development. To meet these challenging goals, Discovery Research has rapidly put into place within the new sanofi-aventis perimeter, a global organization where research activities are performed in Therapeutic Sectors complemented by Support Departments:

In 2004, Discovery Research has contributed to the Development pipeline by entering 10 candidate molecules into preclinical development (the preliminary stage of the development process see Portfolio below):

SSR180711A, a nicotinic alpha-7 receptor partial agonist, for the symptomatic treatment of Alzheimer disease and schizophrenia;

SSR126374P, a CRF1 receptor antagonist, for the treatment of depression and anxiety;

SSR101010, a FAAH inhibitor, for the treatment of anxiety and pain;

SSR103800A, a glycine transporter 1 inhibitor, for the treatment of schizophrenia;

AVE8112A, a phosphodiesterase IV inhibitor, for the symptomatic treatment of Alzheimer's disease;

AVE1876A, a GABA-B receptor antagonist, for depression and anxiety;

Edgar Filing: SANOFI-AVENTIS - Form 20-F

AVE8923A, a tryptase inhibitor, for the treatment of asthma;

AVE4454A, a NHE-1 inhibitor, for acute cardio-protection; and

AVE9423A and AVE2865A, two glycogen phosphorylase inhibitors, for the treatment of type 2 diabetes.

While sanofi-aventis already has a strong Central Nervous System portfolio, these molecules will further increase our potential to obtain new treatments in this difficult therapeutic area where unmet medical needs in particular in schizophrenia and Alzheimer's disease are still very high.

Development

To achieve the goals set for sanofi-aventis Scientific and Medical Affairs, the Development organization needs to be focused, controlled, pragmatic and flexible despite its size and geographical dispersion. It relies, for these reasons, on a strong matrix organization that leads and coordinates the efforts and expertise of representatives from all functions, and at all stages from preclinical to marketing. All members of the Development team work together in synergy to register and deliver innovative new medicines to patients worldwide, while meeting critical strategic, technical and time-to-market requirements, and according to our high standards of quality and ethics.

Table of Contents

One major principle of our matrix organization is the continuity of development from the very beginning (when a molecule enters Development from Discovery) to the end of development (until the project is terminated or until the last potential approval is obtained). A project is defined by one molecule, even if multiple indications are possible. When a molecule enters development, a project team is formed with representatives from all relevant functions (including pharmacologists, clinicians, chemists, toxicologists, regulatory affairs, marketing and many others) who will work together throughout the life of the molecule in development. Development ends when the last potential indication has been approved by regulatory authorities, which can sometimes be many years after the first registration is obtained in the United States and Europe. Practically, these teams may work together for more than 10 years on the development of a high-potential drug like Plavix[®], Lovenox[®] or Eloxatine[®]. Another specificity of our matrix organization is the use by all actors of a unified planning tool, with one planning language and shared methods. Throughout development, our global organization aims at strategic and operational excellence, two key success factors.

In addition to matrix organization, we have put in place strong, well organized and efficient functional structures throughout Scientific and Medical Affairs. For instance, in our clinical development organization, emphasis has been placed on:

The extension of the International Clinical Research Units (CRU) network, with the implementation of a CRU in Russia, leading to a total of 23 CRUs covering more than 35 countries via several regional platforms. Clinical Research Units are hosted in the medical departments of our local affiliates, but are entirely dedicated to the timely execution of the R&D clinical programs,

The increased use of Information Technologies within clinical operations. The use of electronic data capture, transfer validation and online access leads to improved clinical timelines and enhanced quality control.

Finally, well-identified decision-making bodies and processes, involving members of Scientific and Medical Affairs senior management team, have been put in place, to insure adequate decisions are made rapidly, documented and implemented immediately.

In addition, sanofi-aventis Scientific and Medical Affairs capacities have been significantly reinforced in Japan.

Portfolio

As described above, the research and development process historically takes from 10 to 15 years from discovery to initial product launch and is conducted in various stages. During the pre-clinical stage, research scientists perform pharmacology and toxicology studies in various animals. Before testing in humans, an application for the compound must be filed with and approved by the requisite regulatory authorities. Testing in humans is performed in different clinical phases to demonstrate the safety and efficacy of a new compound:

Phase I. In clinical phase I, studies are performed on healthy human volunteers to obtain information concerning safety, preliminary dose-ranging, pharmacokinetics and preliminary interaction with other medications.

Phase IIa. In clinical phase IIa, studies are performed to research the pharmacological activity of the dose range determined in the phase I studies and/or to assess preliminary therapeutic activity in patients.

Phase IIb. In clinical phase IIb, the aim is to determine the risk/benefit ratio, i.e., to demonstrate the clinical activity and to determine the optimal dose in a larger and more varied population.

Phase III. In clinical phase III, we verify the clinical efficacy of the compound on a large population of patients (usually between 3,000 and 5,000 volunteers). These studies involve control groups taking a reference compound or a placebo (an inactive compound identical in appearance to the study compound).

Together, phases IIb and III typically take from three to five years to complete. Thereafter, an application containing all data for the proposed drug is sent to regulatory authorities for approval, which may take an additional six months to two years or longer. There are two types of further clinical trials: one called phase IIIb,

Table of Contents

where new indications are sought; and one called phase IV trials, which are generally carried out after product launch to continue to monitor the efficacy and safety of a new drug.

A rich, innovative and balanced R&D portfolio

The table below shows the composition of the sanofi-aventis R&D portfolio as of the first quarter of 2005:

	<u>Preclinical</u>	<u>Phase I</u>	<u>Phase IIa</u>	<u>Phase IIb</u>	<u>Phase III</u>	<u>Launched / LCM</u>
Cardio-vascular	AVE0657	HMR1069	AVE0118	XRP0038	dronedarone	Tritace® Aprovel®
	AVE1231	AVE9488	HMR1766	SSR 149744		
	AVE3085	SL 65.0472	AVE7688			
	AVE4454					
	AVE4890					
Thrombosis	AVE3247	AVE5026	SSR 182289	otamixaban	idraparinux	Lovenox® Plavix®
	AVE6324	SSR 126517		SR 123781		
	SSR 128428					
	SSR 128429					
Metabolic disorders	AVE0897	AVE0847	AVE0010	SR 147778	Acomplia (rimonabant) Exuberan®**	Amaryl® Lantus® Apidra®
	AVE2865	AVE1625*				
	AVE5376	AVE2268				
	AVE9423	AVE5530				
	SSR 162369	AVE5688 AVE8134				
Oncology	AVE1642	AVE0005	XRP6258	SR31747	XRP9881	Eloxatine®
	CEP11981/SSR106462	AVE8062	uvidem	meclinetant	tirapazamine	Fasturtec®
	AVE9633	SSR 125329			xaliproden*	Taxotere®
	SSR 97225	CEP7055				
	SSR 128129 SSR 244738 SSR 250411					
Central Nervous System	AVE1876	AVE1625*	HP184	M100907	teriflunomide	Rilutek®
	AVE8112	AVE9897*		SR 57667	SR 58611	Depakine®
	AVE8488	SSR 149415		SSR 591813	xaliproden	Stilnox®
	SSR 101010			SL 65.0155*	zolpidem CR**	
	SSR 103800			eplivanserin	saredutant	
	SSR 125543			osanetant		
	SSR 126374					
	SSR 180711					
	SSR 241586					
	SSR 411298					
SSR 504734						

Edgar Filing: SANOFI-AVENTIS - Form 20-F

	AVE0675	XRP2868	HOE140	SR 140333	Alvesco [®]	Arava [®]
	AVE0950	AVE5883	SL 65.0155*	ciclesonide/	SR 121463	Allegra [®]
	AVE1330	AVE9897*	pleconaril	formoterol	Flisint ^{®**}	Ketek [®]
Internal	AVE1701	AVE9940			(fumagillin)	Actonel [®]
	AVE4221	ferroquine				Xatral [®]
Medicine	AVE8680	SSR 150106				
	AVE8923	SSR 180575				
	SSR 126768	SSR 240600				
	SSR 161421	SSR 240612				

* Compounds all appearing in more than one therapeutic area

** NDAs have been submitted for these products

Table of Contents

Sanofi-aventis Pharmaceutical Scientific and Medical Affairs are undertaking the development of 108 compounds, in six therapeutic areas. We believe this is one of the strongest and more promising R&D portfolios in the pharmaceutical industry, particularly strong in the CNS therapeutic area, where the needs for better drugs to treat neurodegenerative diseases, dementia and psychosis are still considerable, and the oncology therapeutic area. The oncology portfolio of the new Group, with a total of 18 compounds in development, gives us the potential to benefit from synergies from the merger and to obtain even more success in this difficult area, as with Eloxatine[®] and Taxotere[®]. The portfolio is well balanced throughout all our therapeutic areas.

With 68 compounds in early development (preclinical and phase I), and 40 in late development (phase II and III), our pharmaceutical portfolio is also well balanced in terms of phase distribution, with a considerable reservoir of innovative compounds in the early phases and 29 programs in phase IIb and III. In 2005, several submissions are planned, with 2 major ones: rimonabant and dronedarone (see Project Highlights below).

In addition to the 108 compounds undergoing development, sanofi-aventis Scientific and Medical Affairs are also deeply involved in the strengthening of labelling (e.g., registration of new indications, and new formulations) of our already marketed products. In this respect, large clinical life-cycle management programs (LCM) have been launched and are managed by S&MA to further support the growth of drugs like Plavix[®], Lovenox[®] and Taxotere[®] (see details under Principal Products). As shown in the tables above, 18 LCM projects may be added to the 108 development projects to understand the extent of our R&D efforts.

Sanofi-aventis Scientific and Medical Affairs achievements in 2004

The dynamics of the sanofi-aventis portfolio is also illustrated through the R&D achievements and projects highlights in 2004.

In 2004, 10 new compounds entered preclinical development (see Discovery above).

In 2004, 10 compounds entered phase I, phase IIa studies have started for 5 NCEs, 13 phase IIb programs (including two in Japan) have started for 12 molecules and 4 phase III programs have been initiated in various indications like breast cancer (XRP9881, new taxane), multiple sclerosis (teriflunomide), major depressive disorders (saredutant) and hyponatremia (SR121463).

In terms of regulatory submissions and approvals, 2004 has also been a fruitful year for sanofi-aventis. 34 files have been submitted in the United States, Europe or Japan for NDAs, defined as the first indication submitted for a new chemical entity, and sNDAs, defined as complementary indications or line extensions for products already on one of the major markets (EU, United States, Japan) See Regulation below.

Two major NDAs have been submitted in the United States and Europe for Exubera[®] (inhaled insulin) and for Ambien[®] CR/Stilnox[®] CR/Stilnoxium, the controlled release formulation of zolpidem (submitted in the United States, France and Switzerland; the mutual recognition process should be initiated in Europe in 2005). One NDA has been submitted in France for Flisint[®] (fumagillin), a very potent treatment for a very rare disease (microsporidiosis in severely immuno-suppressed patients), which exemplifies that sanofi-aventis is dedicated to the development of effective drugs for unmet medical needs, even for small populations. Flisint[®] has been granted an orphan drug status in Europe. In Japan, two NDAs have been submitted, for Plavix[®] (stroke) and for Allegra[®] (pediatric indication).

Edgar Filing: SANOFI-AVENTIS - Form 20-F

27 sNDAs have been submitted in 2004 for major products like Apidra® (metabolic disorders), Ketek®, Lantus®, Taxotere® or Eloxatine®: 14 in the United States, 11 in Europe and two in Japan. Details are given below under [Project Highlights](#) .

In 2004, Apidra® (insulin glulisine) has been approved for the treatment of diabetes in the United States and Europe, and Ketek® was registered in the United States for the treatment of bacterial infections.

21 sNDAs were granted in 2004 or during the first week of 2005 to major products like Taxotere®, Eloxatine®, Allegra® or Lantus®: 8 in the United States, 11 in Europe and 2 in Japan. Details are given below under [Project Highlights](#) .

Table of Contents

Project highlights

LCM development programs for our marketed products are described above in the Products Pharmaceutical Activity .

Cardiovascular and Thrombosis

Certain of our principal compounds in the fields of Cardiovascular and Thrombosis currently in phase IIIb, phase III or phase IIb clinical trials are described below.

Dronedarone (SR33589, atrial fibrillation; phase III). The current reference anti-arrhythmic is still amiodarone, which we have marketed since the late 1960s under the brand name Cordarone®. With dronedarone, a potential successor to Cordarone®, our goal is to develop a new treatment that is at least as effective as amiodarone, but with improved tolerance. The first indication being developed for dronedarone is the prevention of recurrences of atrial fibrillation, the most common cardiac rhythm disorder. The usual treatment for acute atrial fibrillation is an external electric shock to the heart, which is then generally followed by a medicinal anti-arrhythmic agent to avoid recurrences, which are extremely common. The EURIDIS (Europe) and ADONIS (North and South America, Australia and South Africa) phase III trials, involving 1,245 patients with atrial fibrillation have confirmed the good efficacy and safety of dronedarone as an anti-arrhythmic drug, particularly with the absence of any pro-arrhythmic effect. Based on these data, a submission file is currently being prepared and is planned to be discussed with health authorities.

Idraparinix sodium (SR34006, thromboembolic events; phase III). Idraparinix sodium is an injectable synthetic pentasaccharide, selectively inhibiting coagulation factor Xa. Idraparinix sodium has a demonstrated potency and long duration of action that may permit a therapeutic regimen consisting of only one injection per week in humans. Two phase III programs, VAN GOGH and AMADEUS, both of which started in 2003, are ongoing. The VAN GOGH program is studying idraparinix sodium in the long-term treatment of thromboembolic events in patients suffering from deep-vein thrombosis or pulmonary embolism. The AMADEUS program is studying idraparinix sodium in the prevention of thromboembolic events associated with atrial fibrillation.

SSR149744C (atrial fibrillation; phase IIb). Besides the improved tolerability as compared to amiodarone, SSR149744C is expected to be active with a once-a-day dosing. The targeted indication for SSR149744C is atrial fibrillation. SSR149744C entered phase IIb in December 2004.

SR123781 (thromboembolic events; phase IIb). SR123781 is an injectable synthetic oligosaccharide, inhibiting both coagulation factors Xa and IIa. It is a potent antithrombotic drug with a shorter duration of action than idraparinix and it is currently being studied in Phase IIb in patients with arterial thrombosis.

Otamixaban (XRP0673, thromboembolic events; phase IIb). Otamixaban is an injectable non-saccharidic synthetic direct inhibitor of coagulation factor Xa. It exhibits a fast on- and offset of action and represents a promising approach for the initial treatment of ACS.

Metabolic Disorders

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Our main compounds currently in late-stage development for metabolic disorders are described below.

Acomplia (rimonabant, SR141716, metabolic syndrome and weight management, smoking cessation; phase III). Rimonabant is the first in a new class of therapeutics called selective CB-1 receptor blockers. CB-1 receptors were found first in the brain and identified now in several human tissues, including adipocytes. They are part of the endocannabinoid system, which is critically involved in the regulation of body mass and body weight, lipid metabolism and insulin resistance.

Rimonabant is completing a phase III program in obesity, metabolic syndrome and related disorders like type 2 diabetes and dyslipidemia (the RIO program: rimonabant in obesity). This phase III program started in 2001 and is composed of 4 large studies in more than 6,600 overweight patients with co-morbidities and obese patients including severely obese patients (BMI

Table of Contents

over 40). These studies evaluated doses of 5 mg and 20 mg of rimonabant. Results are available from the following completed studies: RIO Lipids in patients with previously untreated dyslipidemia treated with rimonabant or placebo for one year; RIO North America in overweight patients with co-morbidities or obese patients including severely obese patients treated for one year in this study, patients receiving the active treatment were re-randomized for a second year to rimonabant or placebo; and RIO Europe in overweight patients with co-morbidities or obese patients including severely obese patients treated for two years continuously.

Results from the first three studies at one year demonstrated a significant, robust and consistent weight loss (6.3 to 6.9 kg at 20 mg versus 1.5 to 1.8 kg for placebo) and decrease of waist circumference, a marker of visceral fat (6.1 to 7.1 cm at 20 mg versus 2.4 to 2.5 cm in placebo), throughout all the studies. 48% to 58% of patients lost 5% of their weight with 20 mg versus 20% in the placebo group. 25% to 32% of patients on 20 mg lost 10% of their weight versus 7.2% to 8.5% in the placebo groups.

Many obese and overweight persons seen in clinical practice are readily recognized as having multiple cardiovascular risk factors. These individuals are considered to suffer from metabolic syndrome, a condition associated with a core metabolic disorder close to insulin resistance. Patients with metabolic syndrome are at increased risk of coronary heart disease, other diseases related to plaque buildups in artery walls (e.g., stroke and peripheral vascular disease) and type 2 diabetes. The NCEP ATP III panel identified six components of this condition: abdominal obesity, atherogenic dyslipidemia, raised blood pressure, insulin resistance with or without glucose intolerance, pro-inflammatory state and pro-thrombotic state. The panel recommended the use of the following clinical criteria for the diagnosis of metabolic syndrome: waist circumference over 88 cm in women and 102 cm in men, TG higher than or equal to 150 mg/dl, HDL less than 50 mg/dl in women and 40 mg/dl in men, blood pressure higher than 130/85 mmHg and fasting glucose more than 110 mg/dl. A patient meeting three out of five of these criteria is considered to suffer from metabolic syndrome. In the RIO program 40% to 80% of the patients, depending on the study, presented with metabolic syndrome at baseline. In addition to the consistent and robust data summarized above, rimonabant, compared to placebo, statistically decreased the number of patients meeting the criteria of metabolic syndrome at the end of one year of treatment, significantly improved insulin sensitivity, increased HDL (good cholesterol) and decreased triglyceride levels while being well tolerated.

Results at two years from RIO North America demonstrated statistically significant weight loss and decrease of waist circumference while providing improvement of metabolic parameters over the second year compared to patients switching treatment to placebo at the end of the first year. The results at two years from RIO Europe, presented at the American College of Cardiology in March 2005 have further confirmed the efficacy and safety of rimonabant in the long term together with an improvement in cardiovascular risk factors demonstrated over the second year.

The key results of those important studies were presented at major international conferences throughout the year 2004, such as the American College of Cardiology in March 2004 (STRATUS US and RIO Lipids), the European Congress of Cardiology in August 2004 (Rio Europe one year data), and the meeting of the American Heart Association, November 2004 (RIO North America one and two years data).

A fourth study, RIO Diabetes, was completed in 2004. This study included patients with type 2 diabetes mellitus, including overweight patients with co-morbidities or obese patients (including severe obesity), treated for one year. These data will complete the profile of rimonabant in type 2 diabetics. Results from RIO Diabetes will be available in the first half of 2005.

Rimonabant is also being evaluated in smoking cessation in a separate phase III program. The endocannabinoid system is also involved in the sensitivity to positive re-enforcers such as nicotine. Thus CB-1 receptor blockers such as rimonabant may help patients to quit smoking. The medical importance of helping patients to quit smoking is evidenced by the fact that smoking is the second most frequent cause of death and the fourth common risk factor for diseases worldwide. It has been identified as the major preventable risk factor for cardiovascular disease,

Table of Contents

cancer, chronic obstructive pulmonary disease (COPD) as well as type 2 diabetes mellitus. According to the World Health Organization, approximately 1.3 billion people currently smoke worldwide, and cigarette smoking is considered to be responsible for an estimated 5 millions premature deaths each year. While 70% of smokers indicate that they would like to abandon cigarette smoking, only 30% will actually try to quit, and only 3% of attempts will be successful. Moreover smoking cessation is associated with significant weight gain which is a major reason for not trying to quit cigarette smoking. Rimonabant is completing a phase III program in smoking cessation and maintenance (the STRATUS program: Studies with Rimonabant And Tobacco Use). This phase III program started in 2002 and is composed of the following three large studies including more than 5,500 patients: STRATUS US, STRATUS EU and STRATUS WW. In the two short term studies STRATUS US (United States) and STRATUS EU (Europe), patients were treated for 10 weeks and were allowed to smoke at study entry but were given a target quit date at day 15. Efficacy was measured as abstinence from tobacco during the last four weeks of the 10 weeks treatment. Results of STRATUS US are available and showed that rimonabant doubled the odds of quitting cigarette smoking versus placebo while maintaining a well tolerated profile. Moreover, patients on placebo gained more than 2 pounds (1.1kg) while patients treated with the drug lost around just over half a pound (0.3kg). The third long-term study STRATUS WW (worldwide) evaluated the maintenance of abstinence at one year. In this study patients who were abstinent after 10 weeks of treatment with the drug were re-randomised on rimonabant or placebo for one year. Finally, in STRATUS-WW study, rimonabant administered at the dose of 20mg/day was significantly more effective than placebo in the maintenance of abstinence up to one year after smoking cessation, with a good safety profile.

Simultaneous regulatory submission in the United States and Europe for all the indications of rimonabant is planned for first half of 2005 and launch is planned for 2006.

In addition, to the phase III program, a large phase IIIb program has been designed and initiated for rimonabant in 2004. Finally, rimonabant entered phase IIb in Japan.

Exubera® (HMR4006, insulin-dependant diabetes mellitus; submitted) a rapid-acting inhaled insulin that is being co-developed with Pfizer, has been submitted for regulatory approval in Europe and in the United States.

Oncology

The sanofi-aventis oncology portfolio represents a broad spectrum of novel agents with a variety of mechanisms of action for treating cancer and/or cancer side-effects, including cytotoxic agents, anti-mitotic agents, bioreductive agents, receptor antagonists, anti-angiogenic agents, anti-vascular agents, cancer vaccines as well as supportive care therapies. Our principal compounds in the field of oncology currently in clinical trials are described below.

Tirapazamine (SR 259075, head and neck cancer; phase III). Tirapazamine is an anti-cancer agent activated under hypoxic conditions to promote the destruction of resistant hypoxic cells. This innovative mechanism of action is likely to diminish the rate of relapse in tumors associated with hypoxia (i.e. head and neck cancer). Phase III trials on tirapazamine in combination with cisplatin and radiation in head and neck cancer are ongoing. Exploratory Phase I and II studies in other tumors associated with hypoxia are also ongoing.

Meclinetant (SR 48692, small cell lung cancer; phase IIb). Meclinetant is a specific neurotensin receptor antagonist that arrests the growth of tumors (as small cell lung cancer) which are dependent on neurotensin. Currently, meclinetant is being studied in patients with small cell lung cancer as maintenance therapy following standard treatment with cisplatin / etoposide. Additional clinical studies are planned for 2005.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Xaliproden (chemotherapy induced neuropathy; phase III). Xaliproden is an orally active neurotrophic agent which is currently being studied in phase III trials for the treatment of chemotherapy-induced neuropathy.

Table of Contents

XRP9881 (metastatic breast cancer failing taxane therapy; phase III). XRP9881 is a new taxane derivative that has been designed to overcome resistance to existing taxanes, docetaxel and paclitaxel. In phase II, XRP9881 has proved to be active on metastatic breast tumors progressing after taxane therapy. XRP9881 has also been shown to cross the blood-brain barrier, and therefore could potentially be active on brain metastasis.

Genasense[®] (oblimersen sodium). Based on the rejection by the FDA of the application for Genasense[®] in advanced melanoma and on unconvincing results in chronic lymphatic leukemia, we decided to terminate our agreement with Genta for the development of Genasense[®] in November 2004.

Central Nervous System

Certain of our principal compounds in the Central Nervous System field currently in phase II or III clinical trials are described below.

SR58611 (depression; phase III). SR 58611 is a beta-3 adrenergic receptor agonist. This substance stimulates neuronal activity in a specific region of the prefrontal cortex and could give rise to a new class of anti-depressants. In a phase II trial in patients suffering from severe depression with melancholic features, SR 58611 was observed to be superior to fluoxetine, a reference treatment, and was well tolerated. The phase III program is ongoing.

Saredutant (SR 48968, depression; phase III). Saredutant is an NK2 receptor antagonist developed for the treatment of Major Depressive Disorders. The phase III program started end of 2004.

Teriflunomide (HMR 1726, multiple sclerosis; phase III). Teriflunomide is a dihydroorotate dehydrogenase inhibitor. We completed a phase II study in 2003 that showed efficacy and tolerability of teriflunomide in patients with relapsing forms of multiple sclerosis. We initiated an international phase III development program in 2004.

Xaliproden (SR 57746, Alzheimer's disease, neuropathy; phase III -multiple sclerosis; phase II). Xaliproden is a non-peptide compound that activates the synthesis of endogenous neurotrophins. Two phase III studies in Alzheimer's disease are ongoing. Xaliproden is also studied in the oncology area (see above).

SL 65.0155 (Alzheimer's disease; phase IIb urinary urge incontinence; phase IIa). SL 65.0155 is a partial serotonin receptor agonist that has both neuroprotective and memory improving properties. A Phase IIb study in Alzheimer's disease is ongoing with results expected in 2005. A Phase IIa study in urinary urge incontinence was initiated in 2004.

Osanetant (SR142801, schizophrenia; phase IIb). We designed an original study protocol, METATRIAL, to evaluate the therapeutic activity of four compounds possessing novel mechanisms of action in patients with schizophrenia. Osanetant, an NK3 receptor antagonist, showed an activity and a profile close to those of haloperidol, the reference treatment, combined with very good tolerability. Phase IIb is ongoing.

SSR 591813 (smoking cessation; phase IIb). This nicotinic partial agonist is being developed for smoking cessation. We started a Phase IIb program in 2004, with patient inclusion now completed.

SR 57667 (Alzheimer's disease, Parkinson's disease; phase IIb). SR 57667B, like xaliproden, is a non-peptide compound that activates the synthesis of endogenous neurotrophins. One Phase II study is ongoing in Alzheimer's disease. Two phase II studies are ongoing in Parkinson's disease.

Eplivanserin (SR46349, 5HT_{2A} antagonist; phase IIb). This 5HT_{2A} antagonist is being developed for the treatment of sleep disorders (sleep maintenance). A phase II trial in patients with chronic insomnia has been completed. A Phase II study in fibromyalgic patients is ongoing.

M100907 (5HT_{2A} antagonist; phase IIb). This 5HT_{2A} antagonist is being developed for the treatment of sleep disorders (sleep maintenance). A phase IIb program was initiated in 2004.

Table of Contents

HP 184 (spinal cord injury; phase IIa). HP 184 is a potassium channel and use-dependent sodium channel blocker. We completed a Phase II study in 2004 that showed improvement in ASIA Total Motor Score (a measure of sensory and motor function impairment) and confirmed tolerability in patients with spinal cord injury. We initiated a second phase II study in 2004 with the goal to enroll 240 patients globally.

Internal Medicine

Certain of our principal compounds in the field of Internal Medicine currently in clinical trials are described below.

Flisint[®] (fumagillin, SR90144, antibiotic with antiparasitic properties; submitted). An application was submitted in France on December 13th, 2004 for the treatment of intestinal microsporidiosis due to *Enterocytozoon bienewisi* in severely immuno-compromised (HIV-infected) patients. Intestinal microsporidiosis is a rare and debilitating disease that may, in some cases, be life-threatening.

Alvesco[®] (ciclesonide, XRP 1526 asthma; submitted). The U.S. FDA issued an approvable letter for Alvesco[®] metered dose inhaler in October 2004. With our partner ALTANA, we are addressing questions raised by the FDA to ensure the earliest possible approval.

XRP 1526/AVE 2635 (ciclesonide/formoterol, asthma; phase IIb). In addition to Alvesco[®], we are also developing a dry-powder inhaler combination of ciclesonide and formoterol. The first patient was enrolled in a phase IIb clinical study conducted by our partner ALTANA in November 2004.

SR 121463 (Vasopressin V2 receptor antagonist; phase III) is a pure aquaretic compound developed for the treatment of dilutional hyponatremia. Based on the favorable results of the phase IIb study in patients with syndrome of inappropriate antidiuretic hormone secretion (SIADH), a phase III study in SIADH started in the second quarter of 2004. In addition, a large phase IIb program has been initiated in cirrhotic patients in March 2004.

Ferroquine (SSR97193, acute uncomplicated malaria; phase I). Ferroquine is a novel 4-aminoquinoline analogue highly active against both chloroquine sensitive and resistant *Plasmodium falciparum* strains, developed as part of the Impact Malaria program for the treatment of acute uncomplicated malaria. This compound entered phase I in September 2004. Malaria is a disease caused by the parasite *Plasmodium* transmitted to humans by the bite of the *Anopheles* mosquito. Malaria mainly affects the populations of sub-Saharan Africa and, to a lesser extent, Southeast Asia and Latin America. Worldwide there are an estimated 300 million cases of infection per year, and an estimated one to three million deaths per year. Ninety percent of these cases are in Africa and the vast majority are children. Besides the major health problems caused by malaria, the economic impact of the disease is substantial as well, with Africa losing an estimated 1.3% of its growth, or US\$ 12 billion, annually (according to World Health Organization's data).

Collaborative agreements

To support our discovery and development efforts and provide access to new technologies, additional know-how and valuable intellectual property, we have initiated, implemented, continued and modified a substantial number of alliances, partnerships and collaborations with biotechnology, biopharmaceutical and pharmaceutical companies, both at the discovery and development stages.

At the discovery stage:

A partnership initiated in 1999, with **Genfit** (Lille, France) allows studies of novel biological targets in the general area of atherosclerosis and within an exclusive alliance in the PPAR ligands in the fields of type 2 diabetes, metabolic syndrome, multiple sclerosis and inflammation.

An alliance was formed in 2000 with **Millennium** (Cambridge, Massachusetts, U.S.) to bolster our inflammation portfolio by validating novel biological targets and rapidly progressing high-value compounds into the development stage.

Table of Contents

A partnership, started in 1997, with **Cerep** (Rueil-Malmaison, France) aims at extending our general chemical library and screening the new exclusive synthesized libraries on novel biological targets.

A few global licenses have been acquired from **GeneLogic** (Gaithersburg, Maryland, U.S.) to enable the implementation of toxicogenomic technologies and to access expression profiling databases.

A collaboration with **Astex** (Cambridge, UK) has been put in place to measure the binding properties of proprietary compounds with apo P-450 enzymes in order to select the best potential drug candidates.

An agreement with **Amphora** (Durham, North Carolina, U.S.) was initiated in 2004 in order to profile and screen dedicated libraries using microfluid-based compound profiling.

An alliance started in 2003 with **Immunogen** (Cambridge, Massachusetts, U.S.) aims at identifying and developing naked antibodies or immunoconjugates (monoclonal antibodies coupled to an anticancer compound) in the area of oncology, and also covers a technology transfer and a license agreement on three identified products.

A global license and research collaboration has been set with **Coley** (Wellesley, Massachusetts, U.S.) in the area of CpG oligonucleotides acting as immunomodulators, to address diseases in the area of asthma, allergic rhinitis, and chronic obstructive pulmonary diseases.

A long-standing research collaboration with **Mitsubishi Pharmaceutical Corp** (Tokyo, Japan) to identify and develop novel agents in the area of neurodegenerative diseases is being extended.

Within the **Impact Malaria** program, three research alliances have been established. Ferroquine, co-developed with the Université Scientifique et Technique (Lille, France), is currently in Phase I.

At the development stage:

An alliance is in place with **Cephalon** (Westchester, Pennsylvania, U.S.) to discover and develop innovative small molecules acting on VEGF-R tyrosine kinase pathways in the area of angiogenesis. CEP7055 is the current lead compound and is in Phase I.

We have an alliance with **Regeneron Pharmaceuticals Inc.** (Tarrytown, New York, U.S.) on a recombinant fusion protein, VEGF Trap, which acts as a soluble decoy receptor and traps VEGF, thereby inhibiting the interaction with its receptor. Clinical phase I studies are ongoing.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

A partnership initiated in 2001 with **Immuno-Design Molecule** (IDM) (Paris, France) aims at developing autologous cell vaccines, exploiting a cellular therapy technology based on techniques including monocyte maturation using IL 13 for the treatment of various cancers. Uvidem the leading compound of this alliance is developed in the treatment of melanoma and is currently in phase II.

We also have three alliances regarding compounds in late stage development:

We signed an agreement in 2001 with **ALTANA AG** (Bad Homburg, Germany) to jointly develop and market Alvesco® in the United States.

We are developing Exubera® for patients with type 1 and type 2 diabetes through a collaboration with **Pfizer Inc.** (New York, New York, U.S.). Pfizer and us have entered into a global agreement to co-develop, co-promote (where permitted by local law) and co-manufacture inhaled insulin. Pfizer is also in collaboration with Nektar Therapeutics, developers of the inhalation device and formulation. This collaborative agreement is currently the subject of a legal dispute with Pfizer. (See Note D.20.1(b) to our consolidated financial statements included in this annual report at Item 18).

Actonel® is being developed with our alliance partner **Procter & Gamble Pharmaceuticals** (Cincinnati, Ohio, U.S.). More details on this alliance are provided below under [Markets](#) [Alliances](#) .

Vaccines Research and Development

Sanofi pasteur Research and Development is a global force of 1,200 people working across 3 sites. Our human vaccines R&D remains focused on the development of new preventive vaccines, one particular area of research covers novel therapeutic vaccines targeting diseases such as HIV and cancer.

Table of Contents

Key research areas

Dengue - We are undertaking multiple approaches to develop a vaccine covering the four viral serotypes of Dengue fever in order to prevent this disease and its severe complications (hemorrhagic fever), which are prevalent in Asia, Africa and Latin America. This project, currently in phase I, will target people living in affected areas as well as travelers to these regions.

Meningitis (meningococcal) - We are expanding the indications for Menactra[®], a unique conjugate vaccine against the four most prevalent serogroups of *Neisseria meningitidis*. For infants, we are investigating new conjugate vaccine formulations.

Pneumococcal disease - We are undertaking several approaches to develop vaccines to protect elderly adults and also infants against pneumococcal disease.

Influenza - We are looking to new technologies including new delivery modes and new manufacturing processes.

SARS - We have fulfilled our commitment to the U.S. National Institutes of Health (NIH) by delivering Phase I clinical batches according to their specifications and aggressive timelines.

HIV - Sanofi pasteur has been a pioneer in HIV vaccine research due to its long-standing research program as well as partnerships with leading government agencies and pharmaceutical companies. Sanofi pasteur is exploring both prophylactic and therapeutic approaches to developing vaccines to combat HIV.

Cancer - A development program is focusing on colorectal and melanoma cancers, seeking to specifically activate the immune system to destroy cancer cells. Phase I clinical studies using the proprietary ALVAC technology in patients with melanoma and colorectal cancer showed a favorable safety profile.

Sanofi pasteur R&D Pipeline

Key vaccines programs in late-stage clinical development are:

Menactra[®] - the first quadrivalent conjugate vaccine for the prevention of meningococcal meningitis (four serogroups), was submitted for U.S. regulatory approval for use in children age 11 and older as well as adults in December 2003. Unanimous positive votes were given by the Vaccines and Related Biological Products Advisory Committee (VRBPAC) experts to all questions raised by the Center for Biologics Evaluation and Research. Menactra[®] has been approved by the FDA on January 14, 2005. A file will be submitted in Europe and Canada in the beginning of 2005.

Adacel - a trivalent vaccine protecting adolescents and adults against pertussis, diphtheria and tetanus. Marketed in Canada and Germany, Adacel® was submitted for U.S. regulatory approval in August 2004. The VRBPAC meeting of March 18, 2005, voted unanimously to recommend licensure of Adacel.

Pentacel - a vaccine protecting against five diseases (diphtheria, tetanus, polio, whooping cough and Hib meningitis) for the U.S. market will be filed in 2005.

Our early-stage pipeline (phase I/II) includes the following key projects:

DTP-Polio-Hib
Dengue vaccine
Next-generation influenza vaccine
CMV vaccine
ALVAC-HIV vaccine

Novel combination vaccines
Mild to severe dengue fever
Influenza
Prevention of congenital infections, extended indications
Antiretroviral therapy interruption in HIV-positive patients

Table of Contents

Production and Raw Materials

Our principal manufacturing processes consist of three stages: the manufacture of active ingredients, the incorporation of those ingredients into products designed for use by the consumer and packaging. At each of these three stages, we need to purchase a variety of raw materials. When possible, we have a policy of maintaining multiple sources of supply for these materials. In a few cases some raw materials may be in short supply. Nonetheless, we have not experienced any difficulty in obtaining a sufficient supply of raw materials in recent years and believe that we will be able to obtain supplies in sufficient quantities in the future. We are not exposed to any material risk related to the volatility of the prices of raw materials that we outsource.

Regarding the active ingredients that we use in our products, we generally develop and manufacture them ourselves. We have a general policy of producing the active ingredients for our principal products at our own plants rather than outsourcing production. Even though we must outsource certain production elements, we are committed to this general principle, which reduces our dependency on key suppliers.

The production of the active ingredients used in Stilnox[®], Kerlone[®], Xatral[®], Solian[®] and Tildiem[®] is outsourced to Dynamit Nobel, a company to which we sold the related facilities in 2001. Under our current outsourcing agreement, we are required to purchase 50% of our manufacturing requirements of the ingredients for Stilnox[®], Xatral[®] and Solian[®] and all of our manufacturing requirements of the ingredients for Kerlone[®] and Tildiem[®] from these facilities through December 31, 2007.

Among our other key products, we also depend on third parties in connection with the manufacture of Eloxatine[®]. Under the terms of our license agreement, we purchase the active ingredient from Debiopharm, and the production of the finished product is outsourced to two manufacturers. We have scheduled to transfer the manufacture of the liquid form of Eloxatine[®] to our facility in Dagenham (UK).

In addition, we work with external manufacturers mainly for several small products. These subcontractors are required to follow our guidelines in terms of quality, logistics, and other criteria. Our main subcontractors are Patheon, Famar, LCO, Haupt and Sofarimex.

Under our partnership with BMS, a multi-sourcing organization is in place for Plavix[®] and Aprovel[®]. For both products, pharmaceutical production is performed partly in sanofi-aventis plants such as Ambarès and partly in BMS plants. For the active ingredient production, a double-sourcing approach has been put in place for Aprovel[®] involving sanofi-aventis, BMS and sub-contractors' plants.

In mid-2004, we sold the chemical manufacturing plant of Villeneuve-la-Garenne to PCAS. As a consequence we now outsource a part of the chemical activity linked with Lovenox[®] to PCAS (early stages of chemical synthesis), pursuant to a six-year outsourcing agreement.

In connection with the acquisition of Aventis, we divested our interests in Arixtra[®] and Fraxiparine[®]. Our facility at Notre-Dame de Bondeville, which produces those two products, was sold to GlaxoSmithKline on September 1, 2004.

Each stage of the manufacturing process is carried out under carefully controlled conditions and is regulated by applicable legislation and regulatory authorities, including for facilities that produce products marketed in the United States, the FDA. Wherever possible, we seek to have

Edgar Filing: SANOFI-AVENTIS - Form 20-F

at least three plants approved for the production of key active ingredients and finished products.

Our main European production facilities are located in France, Germany, Italy, Spain, the United Kingdom and Hungary. In North America, we run two facilities in the United States (Kansas City and Saint Louis) and one in Canada (Laval). We have one plant in Japan (Kawagoe) and additional facilities located in many other countries around the world including in Northern Africa, Eastern Europe, Asia and Latin America.

All of our facilities are Good Manufacturing Practice (GMP) compliant in accordance with international guidelines. Our main facilities are additionally FDA approved, including facilities in Ambarès, Tours, Le Trait, Maisons-Alfort and Compiègne in France, Dagenham and Holmes Chapel in the United Kingdom, Frankfurt in Germany, Manati in Puerto Rico, Saint Louis and Kansas City in the United States and Laval in Canada.

Table of Contents

To carry out the production of human vaccines, sanofi pasteur has a large industrial operations network with sites located in North America and Europe as well as in emerging markets such as China, Thailand and Argentina.

A more detailed list of our manufacturing sites is set forth below under **Property, Plant and Equipment** .

Markets

Marketing and Distribution

The combination of Sanofi-Synthélabo and Aventis into sanofi-aventis has reinforced the Group's international base and its marketing strength in a number of key markets.

We have a commercial presence in approximately 100 countries, and our products are available in more than 170. Our top five markets are respectively the United States, France, Germany, Italy and Japan. A breakdown of our sales by geographic market is presented in **Item 5. Operating and Financial Review and Prospects - Results of Operations** year ended December 31, 2004 compared with year ended December 31, 2003. Accounting for over 45% of global prescription drug sales, the United States is the world's largest pharmaceutical market and our single largest national market. In 2004, we generated 34.5% of our pro forma net sales in the United States. In Europe, our leading markets are France, Germany, Italy, Spain and the United Kingdom. Japan, the world's second-largest national pharmaceutical market, accounted for 4.5% of our pro forma net sales in 2004.

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed care organizations and government institutions. These drugs are ordinarily dispensed to the patients by pharmacies upon presentation of a doctor's prescription.

We have a global sales force of 33,000 representatives, including approximately 12,000 in Europe, 8,000 in the United States, 1,500 in Japan and 1,000 in China. The precise composition by therapeutic area fluctuates according to business needs and in line with each country's key products. In our major markets, we deploy dedicated sales forces specialized in areas such as oncology, metabolism and cardiovascular diseases.

Our 33,000 medical sales representatives, who work closely with health care professionals, use their expertise to promote and provide information on our drugs. These representatives embody the Group's values on a day-to-day basis and are required to adhere to a code of ethics. In order to maintain a sound relationship with all of our partners, we invest significantly in employee training. This commitment extends to promoting and providing information not only on the latest therapeutic advances but also on all our traditional products, which provide the foundation for satisfying major therapeutic needs. The quality of our sales force teams is recognized by our customers, as highlighted in the U.S. by the Health Strategies Spring 2004 SFE monitor survey. In this survey, both legacy companies ranked in leading positions: one in its ability to access customers and describe on products, and the other in effective approach of calls, by delivering rich content to our customers.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Beyond direct promotion by our sales forces, and as most pharmaceutical companies do, we also market and promote our products to physicians through a variety of advertising, public relations and promotional tools. We regularly advertise in medical journals and exhibit at major medical congresses. In some countries, some of our products are also marketed directly to consumers by way of television, radio, newspapers and magazines. Not all products are marketed through all media channels. National advertising campaigns are used to enhance awareness of conditions such as deep vein thrombosis, osteoporosis, uncontrolled diabetes and influenza in markets such as Germany, France and the U.S. Some major campaigns took place in 2004, such as a direct-to-consumer campaign on Allegra® in the U.S. and a global awareness campaign on the importance of the HbA1c test (a measure of long-term blood sugar level) for diabetic patients.

Although we market most of our products with our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographic areas. Major arrangements currently include an agreement with Bristol-Myers Squibb for the cardiovascular drugs Aprovel® and Plavix®, Procter & Gamble Pharmaceuticals for the osteoporosis drug Actonel® and Teva Pharmaceuticals for the multiple sclerosis drug Copaxone®. More details on these alliances are provided below in under Alliances .

Table of Contents

Our human vaccines are sold and distributed through multiple channels including physicians, pharmacies and distributors in the private sector, and governmental entities and Non-Governmental Organizations (NGOs) in the public and international donor markets, respectively.

Alliances

In 2004, we had three major alliances through which 4 of our top 15 products were marketed. The first, with Bristol-Myers Squibb, or BMS, governs the development and marketing of Plavix[®] and Aprovel[®]. The second, with Procter & Gamble Pharmaceuticals, or P&G, governs the development and commercialization of Actonel[®]. The third is a marketing agreement with Teva regarding Copaxone[®].

The financial impact of our principal alliances on our financial condition or results of operations is significant and is described in detail under Item 5. Operating and Financial Review and Prospects Overview Financial Presentation of Alliances .

Bristol-Myers Squibb

We market Aprovel[®] and Plavix[®] through a series of alliances with BMS. The alliance agreements include marketing and financial arrangements that vary depending on the country in which the products are marketed.

There are three principal marketing arrangements that are used in the BMS alliance:

Co-marketing: Each company markets the products independently under its own brand names.

Exclusive Marketing: One company has the exclusive right to market the products.

Co-promotion: The products are marketed through the alliance arrangements (either by contractual arrangements or by separate entities) under a single brand name.

Under the alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world excluding Japan. In Japan, Aprovel[®] is under development through agreements between BMS and the Japanese pharmaceutical company Shionogi Pharmaceuticals, and Plavix[®] is under development through an alliance between our company and Daiichi Pharmaceuticals Co., Ltd.

In the territory under our operational management, the marketing arrangements are as follows:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

We use the co-promotion system for most of the countries of Western Europe for Aprovel[®] and Plavix[®] and for certain Asian countries for Plavix[®].

We use the co-marketing system in Germany, Spain and Greece for both Aprovel[®] and Plavix[®], and in Italy for Aprovel[®].

We have the exclusive right to market Aprovel[®] and Plavix[®] in Eastern Europe, Africa and the Middle East, and we have the exclusive right to market Aprovel[®] in Asia (excluding Japan).

In the territory under BMS operational management, the marketing arrangements are as follows:

We use the co-promotion system in the United States and Canada, where the products are sold through the alliances under the operational management of BMS.

We use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix[®] and Aprovel[®], and in Colombia only for Plavix[®].

We have the exclusive right to market the products in certain other countries of Latin America.

Table of Contents

In countries where the products are marketed by BMS on a co-marketing basis, or through alliances under the operational management of BMS, we often sell the active ingredients for the products to BMS or such entities.

Procter & Gamble Pharmaceuticals

We in-license Actonel[®] from Procter & Gamble Pharmaceuticals. An alliance with P&G was concluded in April 1997 for the co-development and marketing of Actonel[®]. The 1997 agreements were amended in October 2004 following the acquisition of Aventis by sanofi-aventis.

The alliance agreement with P&G includes the development and marketing arrangements for Actonel[®] worldwide (except Japan). The ongoing R&D costs for the product are shared equally between the parties, while the marketing arrangements vary depending on the country in which the product is marketed.

Under the alliance arrangements with P&G, there are four principal territories with different marketing arrangements:

Co-promotion Territory: The product is jointly marketed through the alliance arrangements under the brand name Actonel[®] with sales booked by P&G. The co-promotion territory includes the United States, Canada, France, Germany, the Netherlands, Belgium and Luxemburg.

Secondary Co-promotion Territory: The product is jointly marketed through the alliance arrangements under the brand name Actonel[®] with sales booked by sanofi-aventis. The secondary co-promotion territory includes the UK and Ireland.

Co-marketing Territory: Each company markets the products independently under its own brand name. Italy is currently the only country in this territory; the product is sold in Italy under the brand name Actonel[®] by P&G and under the brand name Optinate[®] by sanofi-aventis.

Sanofi-aventis Only Territory: The product is marketed by sanofi-aventis independently under the brand name Actonel[®] or another agreed trademark in all other territories.

Pursuant to the 2004 amendment to the alliance agreement, P&G has elected to co-promote, beginning on May 1, 2005, Actonel[®] in the following countries: Sweden, Finland, Switzerland, Austria, Portugal and Australia. These countries will become part of the secondary co-promotion territory described above. P&G may also at a later date decide to co-promote the product in Denmark, Norway, Mexico, Greece and/or Brazil.

Teva

We in-license Copaxone[®] from Teva and market it through an alliance agreement with Teva, which was originally concluded in December 1995, and amended twice, in May 1997 and February 2001.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Under the alliance agreement with Teva, marketing and financial arrangements vary depending on the country in which the products are marketed.

Outside the United States and Canada, there are three principal marketing arrangements under the Teva alliance:

Exclusive Marketing: We have the exclusive right to market the product. This system is used in a number of European countries, South Korea, Australia, New Zealand, India, Taiwan, South Africa and China.

Co-promotion: The product is marketed through the alliance arrangements under a single brand name. We use the co-promotion system in Germany, the UK, France, the Netherlands, Austria, Belgium and the Czech Republic.

Semi-exclusive: Each company markets the product independently under its own brand name. We use this system in Italy.

In the United States and Canada, Copaxone[®] is sold and distributed by sanofi-aventis but marketed by Teva. Following the expiration of an agreement in March 2008, Teva will assume the Copaxone[®] business, including sales of the product, in the United States and Canada.

Table of Contents

Competition

The pharmaceutical industry in which we operate is highly competitive. Over the last few years, the pharmaceutical industry has experienced increased vertical and horizontal consolidation. In addition to the consolidation, significant changes in marketing conditions are occurring in the European, U.S. and Japanese pharmaceutical markets, including decreased pricing flexibility, increased cost control measures, and the impact of managed care, especially with respect to product selections and pricing concessions. As a result of these factors, the breadth of products that we offer and our distribution capabilities have become increasingly important.

The pharmaceutical market is generally defined by three types of competition:

competition among pharmaceutical companies to develop new patented products for a specific therapeutic indication;

competition among patented pharmaceutical products for a specific therapeutic indication; and

competition among original products with generic bioequivalent products following the loss of patent protection.

We compete with other pharmaceutical companies to develop new and innovative pharmaceutical products. We may develop new technologies and new patented products entirely internally, or we may enter into collaborative research and development arrangements in order to access additional new technologies. When we wish to have access to new technologies through outside research and development collaborative arrangements, we compete directly with large pharmaceutical companies.

Our prescription drugs compete in all our major markets primarily against other branded, patented drugs from large national and international pharmaceutical companies, e.g., Novartis in hypertension and oncology, Pfizer in antibiotics, oncology and allergy, AstraZeneca in cardiovascular and oncology, Bristol-Myers Squibb in oncology, Boehringer-Ingelheim in atherothrombosis and benign prostatic hyperplasia, Eli Lilly in osteoporosis, diabetes, and oncology, GlaxoSmithKline in oncology, allergy and thrombosis, Merck & Co. in hypertension, osteoporosis and benign prostatic hyperplasia, Abbott in benign prostatic hyperplasia, Novo Nordisk in diabetes and Roche in oncology. In the human vaccines business, we compete primarily against GlaxoSmithKline, Merck & Co, Wyeth and Chiron.

Note: The following market share and ranking information is based on sales data from IMS Health MIDAS and GERS (France), retail and hospital, for the year 2004, in constant euros. While we believe the IMS/GERS sales data we present below are generally useful comparative indicators for our industry, they may not precisely match the sales figures published by the companies that sell the products (including our company and other pharmaceutical companies). In addition, the rules used by IMS to attribute the sales of a product covered by an alliance or licence agreement do not always exactly match the rules of the agreement, and therefore an exact comparison of IMS sales and our pro forma net sales is not possible.

The IMS-consolidated sales perimeter presents sales as reported by IMS, except that German data has been adjusted to account for parallel trade (described below) because of its importance. The IMS-developed sales perimeter includes both our IMS-consolidated sales and 100% of the sales of the following products, whether attributed by IMS to sanofi-aventis or our alliance partners:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Plavix[®], Avapro[®]/Avalide[®] and Copaxone[®] in the United States and Canada,

Kerlong[®], Milrila[®], Ganaton[®] Fujisawa, Meilax[®], Miradol[®], Barnetil[®] Schering, and Barnetil[®] Dainippon in Japan.

United States

In the U.S. prescription drug market, we rank ninth based on IMS-consolidated sales and fifth based on IMS-developed sales. Our market share is 4% based on IMS-consolidated sales and 5.7% on IMS-developed sales. In 2004, our top-selling products and their market shares in the U.S. were Plavix[®] (71.3%), Stilnox[®] under the brand name Ambien[®] (89.0%) and Allegra[®] (38.9%).

Table of Contents

Canada

In Canada, sanofi-aventis ranks ninth based on IMS-consolidated sales and fifth when taking into account IMS-developed sales, with a market share of 3.7% for IMS-consolidated sales and 5.6% for IMS-developed sales. In 2004, our top-selling products and their market shares were Tritace[®] under the brand name Altace[®] (44.3%), Plavix[®] (64.7%) and Aprovel[®]/CoAprovel[®] under the brand name Avapro[®]/Avalide[®] (24.1%).

France

In France, we are the number one pharmaceutical company, with a market share of 16.4%. Our top-selling products and their market shares were Plavix[®] (76.6%), Lovenox[®] (61.8%) and Vasten[®] (13.6%).

Germany

In Germany, we are now the first pharmaceutical company, with a market share of 6.9%. Our largest products and their market shares are Plavix[®] (41.2%), Lovenox[®] (41.9%), and Insuman[®] (17.5%).

Japan

In Japan, where we have a market share of 2.1% based on IMS-consolidated sales and 2.3% on IMS-developed perimeter, we ranked 17th and 13th based respectively on IMS-consolidated and IMS-developed sales. Our top-selling products and their market shares were Allegra[®] (17.7%), Amaryl[®] (11.2%) and Stilnox[®] under the brand name Myslee[®] (24%).

We also face competition, sometimes significant, from generic prescription products, which typically enter the market as patent protection and regulatory exclusivity expire, but they may also gain entry to the market through successfully challenging our patents. More details on such challenges are provided under at Item 8. Financial Information Consolidated Statements and Other Information Information on Legal or Arbitral Proceedings and at Note D.20.1(c) to the consolidated financial statements included in Item 18 of this annual report. Sanofi-aventis is also subject to competition from over-the-counter and behind-the-counter products (drugs available without a prescription but only dispensable by a trained pharmacist) which are generally sold at a lower price than branded prescription drugs. This is often the case when, for example, a significant competing prescription drug switches to over-the-counter status, or a competing product sold by prescription in some countries is sold behind-the-counter in a country where our product is sold by prescription only.

Another competitive issue facing pharmaceutical manufacturers is the increasing incidence of parallel trade, also known as re-importation, which takes place when drugs sold abroad under the same trade name as in a domestic market are then imported into the domestic market by parallel traders, who may repackage and/or resize the original branded product or offer products for sale by alternative means, such as by mail or the internet. The rationale for parallel imports lies in economic advantages arising from different prices for the drugs due to different sales costs, market conditions (e.g., intermediate trading stages) and tax rates or because of national regulation of prices. There are indications that parallel trade is affecting markets in several regions, including the European Union, the United States, South Africa, the Philippines, India, Russia and

Israel.

Regulation

The international pharmaceutical industry is highly regulated. National and supranational regulatory authorities administer numerous laws and regulations covering the testing, approval, manufacturing, importation, exportation, labeling and marketing of drugs, and also review the quality, safety and efficacy of pharmaceutical products. Of particular importance is the requirement to obtain and maintain regulatory approval for a pharmaceutical product from a country's national regulatory authority before such product may be marketed in that country and thereafter. These regulatory requirements are a major factor in determining whether a substance can be developed into a marketable product and the amount of time and expense associated with such development.

The submission of an application to a regulatory authority does not guarantee that a license to market the product will be granted. Furthermore, each regulatory authority may impose its own requirements and may refuse to grant, or may require additional data before granting, an approval, even though the relevant product has been

Table of Contents

approved in one or several other countries. Regulatory authorities also have administrative powers that determine product recalls, seizure of products and other sanctions.

Europe, the United States and Japan all have very high standards for technical appraisal. The length of time required to obtain approval varies by country, but generally takes from six months to, in some cases, several years from the date of application, depending on the quality of data produced, the degree of control exercised by the regulatory authority, the review procedures and the nature of the product.

In recent years, intensive efforts have been made among the United States, the European Union and Japan to harmonize registration requirements. Many pharmaceutical companies are now able to prepare a common technical document, or CTD, that can be used in each jurisdiction for a particular product with only local or regional adaptation.

However, the requirement of many countries (including Japan and several member-states of the EU) to negotiate selling prices or reimbursement levels with government regulators can substantially extend the time to market after initial approval to market is granted.

In the EU, there are two main procedures by which to apply for marketing authorization, namely the Centralized Procedure and the Mutual Recognition Procedure.

The Centralized Procedure is compulsory for medicinal products derived from biotechnology and is also available at the request of companies for other innovative products. In the Centralized Procedure the license application is submitted directly to the European Agency for the Evaluation of Medicinal Products (EMEA). The application is evaluated by the Committee for Medicinal Products for Human Use (CHMP). The European Commission makes the final binding decision. Once granted, an approval via the Centralized Procedure is valid throughout the European Union without further action and the drug may be marketed within all EU member states.

The Mutual Recognition Procedure operates by having one country (i.e. the Reference Member State (RMS)) carry out the primary evaluation of a new compound. Once the first license is granted by the RMS other EU member states (Concerned Member States) then must decide whether they will accept or reject the approval granted by the RMS.

National authorizations are still possible but are only for products intended for commercialization in a single EU member state, or for line extensions to existing national product licenses.

In the United States, applications for drug registration are submitted to and reviewed by the FDA. The FDA has broad regulatory powers over all pharmaceutical products that are intended to be, and which are, commercialized in the United States. To commercialize a product in the U.S., an NDA is filed with the FDA with data that sufficiently demonstrate the drug's quality, safety and efficacy. Approval for a new indication of a previously registered drug requires the submission of an sNDA.

Generic drug manufacturers may file an ANDA. These applications are abbreviated because generic manufacturers need only to demonstrate that their product is bioequivalent (i.e., that it performs in the same manner as the innovator's drug). Consequently, the length of time for development of such product can be considerably shorter than for the innovator's drug.

Once marketing authorization is granted, the new drug (or new indication) may be prescribed by physicians. Thereafter, the drug owner must submit periodic reports to regulatory authorities including any cases of adverse reactions. For some medications, regulatory authorities may require additional studies to evaluate long-term effects or to gather information on the use of the product under special conditions. In addition, manufacturing facilities must be approved by regulatory authorities, and are subject to periodic inspections. Non-U.S. manufacturing facilities that export products for sale in the United States must be approved by the FDA in addition to local regulatory approvals, and are also subject to periodic FDA inspections.

In Japan, the regulatory authorities can request bridging studies to verify that foreign clinical data are applicable to Japanese patients and also require data to determine appropriateness of the dosages for Japanese patients. These additional procedures have in the past created differences of several years in the registration dates of some of our products in Japan compared to our other major markets.

Table of Contents

All our manufacturing facilities must also be Good Manufacturing Practice (GMP) compliant. GMP is a term that is used internationally to describe a set of principles and procedures that, when followed by manufacturers of therapeutic goods, helps ensure that the products manufactured will have the required quality for human use. A basic tenet of GMP is that quality cannot be tested in a batch of product but must be built into all stages of the manufacturing process. These quality system regulations include requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling and storing pharmaceutical products, including guidelines relating to the installation and servicing of the equipment used in drug manufacture. Compliance with specified GMP requirements is used by most countries as the basis for licensing the manufacturer of pharmaceutical products.

Pricing

In most markets in which we operate, governments exercise some degree of control over pharmaceutical prices. The nature of these controls and their effect on the pharmaceutical industry vary greatly from country to country. In recent years, national healthcare reimbursement policies have become more stringent in a number of countries in which we do business as part of an overall effort to reduce the cost of healthcare. Different methods are applied to both the demand and supply side to control pharmaceutical costs, such as reference pricing, patient co-payment requirements, reimbursement limitations and volume containment measures, depending on the country.

We believe that the governments in many markets important to our business will continue to enact measures in the future aimed at reducing the cost of pharmaceutical products to the public. It cannot be predicted with certainty what future effects the various pharmaceutical price control efforts will have on our business. These efforts could have significant adverse consequences for the pharmaceutical industry as a whole and, consequently, also for sanofi-aventis. Increasing budgeting and price controls, the inclusion of patent protected drugs in fixed price systems and approved drug lists and other similar measures may continue to occur in the future.

United States

In the United States, Medicaid, Medicare and other healthcare programs govern provider reimbursement levels in many cases. The Medicaid program requires that pharmaceutical manufacturers pay rebates to individual states on Medicaid reimbursed pharmaceutical products so that the Medicaid program receives the manufacturer's best price or a minimum discount provided by law. U.S. federal and state governments are actively seeking ways to reduce the costs of pharmaceutical products paid for with federal and state funds. In 2003, legislation was passed that added a prescription drug benefit to the Medicare program. Further attempts to reform Medicaid and Medicare may occur, potentially shifting public sector beneficiaries from traditional fee-for-service coverage into managed care plans. Legislation concerning re-importation, marketing practices and pricing policies is also pending at the Federal and State levels.

France

In France, the government regulates prices of new prescription drugs and price increases of existing drugs. In 2002, the French government introduced a set of healthcare reforms known as the *Mattei Plan*. This plan was aimed at redefining reimbursement conditions and criteria for the pricing of pharmaceutical products through the Transparency Committee and the Drug Pricing Committee, and encouraging generic drug development. A new reference pricing system was introduced in France in July 2003 under which the government reimburses off-patent products only up to a certain level with patients paying the remainder. In addition, the French health ministry de-listed several products deemed to have insufficient medical benefit. In return, the government introduced the principle of a fast-track procedure to set prices and provide reimbursement for new innovative drugs. This measure could extend by many months the duration of commercialization for drugs under patent protection. In July 2004, the French Parliament passed a Health Insurance Bill (*Projet de Loi Relatif à l' Assurance Maladie*) with the objective to

Edgar Filing: SANOFI-AVENTIS - Form 20-F

reduce costs by around 10 billion per year and to raise additional revenues totaling 5 billion per year. A major impact on the pharmaceutical industry will be that if health insurance spending on drugs increases by more than the government's target of 3% in 2004 and 1% per annum in subsequent years, the pharmaceutical industry will be required to pay rebates equivalent to up to 70% of the excess. Beginning January 1, 2005, a new organization, the High Authority for Health (Haute Autorité de la Santé), will evaluate medicines and other forms of treatment, offer recommendations on what the health insurance system should reimburse, and issue guidelines on good clinical practice.

Table of Contents***Japan***

The Ministry for Health, Labor and Welfare (MHLW) controls the pricing of pharmaceutical products in Japan. The MHLW determines the drug reimbursement price paid by the National Health Insurance (NHI) to medical institutions. The NHI drug reimbursement price is determined for each prescription drug by the MHLW. The price of a new drug is based on the daily price of comparable drugs, with certain premiums added as necessary. Since the price at which medical institutions purchase drugs can be set at a lower price than the reimbursement price through negotiation with wholesalers, a gap may exist between the selling price and the NHI drug price. Periodically (every two years in principle), the MHLW carries out a revision of drug reimbursement prices aimed at bringing NHI prices closer to the market prices. The latest pricing round in April 2004 averaged a decrease of 4.2%, which was the lowest in two decades.

Germany

Since the late 1980s, the German government has imposed a wide range of supply- and demand-side restrictions intended to curb the level of overall spending on pharmaceuticals. A reference pricing system that requires patients to pay the difference between the actual price of the prescribed drug and the reference price has been in existence since 1989. In practice, patients are generally not willing to pay the difference. As a result, pharmaceutical companies face the decision either to reduce prices to the reference price level or risk a substantial drop in prescriptions. In 1996, the German government suspended reference pricing for all patent-protected drugs approved in Germany after December 31, 1995. In 2004, reference pricing for patent-protected drugs was re-introduced by the new healthcare legislation. Patent-protected drugs without demonstrable therapeutic superiority according to the criteria of the Joint Federal Committee can be subject to reference pricing.

Further to reference pricing, individual prescription limits for physicians were introduced in 2001, which have to be negotiated annually between the Statutory Health Insurance (SHI) and the National Association of SHI-accredited Physicians. The legislation is also aimed at increasing the prescription of generic and imported drugs. In 2002, a sales quota for imported drugs came into force. Pharmacists were obliged to fulfill an import quota of 5.5% in 2002 and 7% in 2003, respectively. The new healthcare legislation reduced the import quota to 5% in 2004. In addition, pharmacies were obliged to dispense parallel imports only, if the imported drug is 15% or 15 cheaper than the original drug. In 2003, a price freeze and a compulsory rebate of 6% for all prescription drugs not covered by reference pricing came into force. In 2004, this rebate was increased to 16%, limited until the end of 2004. The price freeze ended in December 2004 and the compulsory rebate was reduced to 6% in January 2005.

Italy

A reference price reimbursement system has been in place in Italy since September 2001. The reference price is currently calculated as the price of the cheapest drug in the category at regional level. Beginning January 2004, a new public body, the Italian medicines agency (AIFA), has taken over all the responsibilities covering medicine approval, pricing and reimbursement, as well as pharmaceutical expenditure in general. The AIFA has the authority to reassess the reimbursement list on an annual basis and decide which changes need to be implemented. In June 2004 the AIFA imposed a 6.8% price cut on the ex-factory price of all reimbursed medicines, equivalent to a 4.12% reduction of the reimbursed public price level. In line with its powers, the AIFA has approved a restructuring of the reimbursement list (*Prontuario*) that involves price cuts for almost 300 high-selling presentations and an increase in the number of drugs for which patients do not have to pay. As a result, the number of fully reimbursed medicines, both patented and generic, increased. To help to offset the cost of this decision and to rein in the expected overshoot in pharmaceutical spending for 2004, as well as cap the growth for 2005, the AIFA has approved the following measures:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

(a) Reduction of the retail public price affecting 294 product presentations (for a total of 56 active ingredients) was implemented on January 1, 2005. These are the active ingredients that had in the first half of the year 2004 a sales increase beyond the average of the whole market (+8.6%). Prices can be reduced by a maximum of 10%.

(b) Extension of the current compulsory 6.8% reduction of the ex-factory price up until the end of 2005.

Table of Contents

The two measures are cumulative. Hence the 294 high selling presentations will be subject to both price cuts.

United Kingdom

The Department of Health has power, now contained in the Health Act 1999, to limit prices of pharmaceuticals and control the profits of pharmaceutical companies. Against this background, a voluntary agreement called the Pharmaceutical Price Regulation Scheme (PPRS) has been concluded between the industry association and the Department of Health. Within a framework relating to profit, manufacturers are free to set initial prices but restricted in making subsequent price changes. The previous form of the PPRS was running from 1999 to 2004. In November 2004 the Department of Health announced that it had re-negotiated the PPRS for the next five years for the period through 2010 including a 7% price cut on branded prescription drugs. The National Institute for Clinical Excellence (NICE) is empowered to issue guidelines in relation to therapeutic areas and guidance on the clinical effectiveness and cost effectiveness of particular treatments. Guidance by NICE influences the extent to which supply of the product is financed within the National Health Service.

Spain

The Spanish health care system has traditionally offered its beneficiaries very generous reimbursement terms for prescription drugs. Nevertheless drugs prices are generally lower than in other major markets. Companies must negotiate the price of a reimbursable drug with the Central Government. In addition the recent decentralization of health care has a powerful influence on the evolution of the market, as regional governments want greater control over the pricing and reimbursement. The Spanish health ministry has announced a large number of measures (included in the Strategic Pharmacy Policy Plan) to reduce drug spending. The proposed 67 measures include a reduction in drug prices of 4.2% in 2005 and another 2% in 2006, a modification of the reference pricing system to boost the generic market and the rewarding of a true innovation through the introduction of a pricing and reimbursement scale that will set the prices of new drugs according to their degree of therapeutic superiority over established treatments. On the other hand the government has decided not to renew the three-year old stability pact with the pharmaceutical industry and to introduce a sales tax.

Patents, Intellectual Property and Other Rights

Patents

We currently own approximately 49,000 patents, patent licenses and patent applications worldwide. These patents cover:

active ingredients,

pharmaceutical formulations,

product manufacturing processes,

intermediate chemical compounds used in manufacturing, and

therapeutic indications.

Patent protection for individual products typically extends for 20 years from the patent filing date in countries where we seek patent protection. This protection may be further extended in some countries, in particular in Europe, the United States and Japan. The protection afforded depends upon the type of patent and its scope of coverage and may also vary from country to country. In most industrial countries, patent protection exists for new active substances and formulations, as well as for new indications and production processes. We monitor our competitors and vigorously challenge patent and trademark infringements.

The expiration of a product patent may result in significant competition from generic products against the covered product and, particularly in the United States, can result in a dramatic reduction in sales of the pioneering product. In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets, patents on processes and intermediates for the economical manufacture of the active ingredients, patents for special formulations of the product or for delivery mechanisms, and conversion of the

Table of Contents

active ingredient to OTC products. In some countries, including Europe and the United States, many of our products may also benefit from a 5-to-10-year market exclusivity period. This exclusivity period operates independently of patent protection and may protect the product from generic competition even if the basic patent for the product has expired.

Among our top fifteen products in terms of 2004 sales, Tritace[®] no longer enjoys any kind of patent protection in several major markets including Germany. For certain of our other top fifteen products, including Allegra[®], Amaryl[®] and Depakine[®], the main patent has expired and we only have patent protection on a particular formulation of the drug or on a manufacturing process in certain countries. For Plavix[®] there are three U.S. patents, one expiring in 2011 and two expiring in 2019, and national patents issued from two European patents, expiring in 2013 and 2019, respectively. Aprovel[®] is protected in the United States until 2011 and in Europe until 2012. For Lovenox[®] our principal U.S. patent expires in 2012. Stilnox[®] began to lose some of its patent protection in 2002 followed by the expiration of French patent protection in 2004. Its main remaining patents will expire in 2006 (United States and Japan). Three of our top fifteen products, Eloxatine[®], Copaxone[®] and Actonel[®], are marketed under licensing agreements. We do not own the Eloxatine[®] patents but in-license them from a third-party for marketing. The main patent has expired and the other patents expire in 2013 and 2015. Copaxone[®] is co-promoted by sanofi-aventis and Teva, and its principal patents expire 2014. We co-market Actonel[®] with Procter & Gamble Pharmaceuticals, which holds the NDA for this product in the United States. The U.S. patent on the active ingredient expires in December 2013 and the U.S. formulation patents expire in 2017.

One of the main limitations on our operations in some countries outside the United States and Europe is the lack of effective intellectual property protection of our products. Under international agreements in recent years, global protection of intellectual property rights is improving. The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), which forms part of the General Agreement on Tariffs and Trade, requires developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products by January 1, 2005 although it provides a limited number of developing countries an extension to 2010. While the situation has gradually improved, the lack of protection for intellectual property rights poses difficulties in certain countries.

In the United States and other major markets, companies have filed Abbreviated New Drug Applications, or ANDAs, challenging patents related to a number of our products. See Item 8. Financial Information Consolidated Statements and Other Information Information on Legal or Arbitral Proceedings and Note D.20.1(c) to the consolidated financial statements included at Item 18 of this annual report. An ANDA is an application by a generic manufacturer for approval of a generic product prior to the expiration of the related patents. See Regulation above. We intend to defend our patent rights vigorously in these cases.

Trademarks

Our products are sold around the world under brand-name trademarks that we consider to be of material importance in the aggregate. It is our policy to register our trademarks worldwide, and to monitor the trademarks in our portfolio and defend them worldwide.

The degree of trademark protection varies country by country, as each state implements its own laws applicable to trademarks used in its territory. In some countries, trademark protection is primarily based on use, whereas in other countries, trademark rights may only be obtained by registration. Registrations are generally granted for a fixed term (in most cases ten years) and are renewable indefinitely, but in some instances may be subject to the continued use of the trademark. When trademark protection is based on use, it covers the products and services for which the trademark is used. When trademark protection is based on registration, it covers only the products and services designated in the registration. We usually register our trademarks for pharmaceutical products in class 5, although we sometimes are required, subject to local trademark law, to further specify the type of product protected by the trademark. Additionally, in certain cases, we may enter into a coexistence agreement with a third-party that owns potentially conflicting rights in order to better protect and defend our trademarks.

Table of Contents

Health, Safety and Environment

Our manufacturing and research operations are subject to increasingly stringent health, safety and environmental laws and regulations. Such laws and regulations are complex and rapidly changing. We have made, and intend to continue to make, necessary expenditures for compliance with them. Our expenditures related to health, safety and environmental compliance vary from year to year. In 2004, we invested more than 89 million in health, safety and environmental compliance. While we cannot predict with certainty the future costs for compliance, we believe that our designated provisions are adequate based on currently available information. However, given the inherent uncertainties in projecting environmental liabilities we cannot guarantee that additional costs will not be incurred beyond the amounts accrued.

The environmental laws and regulations that we are subject to may require us to remove or mitigate the effects of the disposal or release of chemical substances at our various sites. Under some of these laws and regulations, a current or previous owner or operator of a property may be held liable for the costs of removal or remediation of hazardous substances on, under or in its property, or transported from its property to third party sites, without regard to whether the owner or operator knew of, or caused the presence of, the contaminants. The current or previous owner may also be liable regardless of whether the practices that resulted in the contamination were legal at the time they occurred.

Because certain of our manufacturing sites have an extended history of industrial use, and because of Aventis' legacy of environmental remediation obligations inherited from its former chemical and agrochemical businesses, it is impossible to predict precisely what effect these laws and regulations will have on us in the future. As is typical for companies involved in the pharmaceutical, chemical and agrochemical industry, soil and groundwater contamination has occurred in the past at some of our sites, and might occur or be discovered at other sites. Such sites are mainly located in the United States, Germany, France and Brazil. In connection with environmental audits conducted in the previous years, many assessments of soil and groundwater contaminations were conducted at operating sites and non operating sites and we are now in the process of reviewing required remediation works in cooperation with national and local authorities and are rehabilitating or monitoring remediation works at many sites. Among them, remediation work is completed or in progress at sites including Rochester and Cincinnati in the United States, Frankfurt/Hoechst in Germany, and Beaucaire, Limay, Massy, Rousset and Valernes in France. We have also been identified as having potential liability for investigation and cleanup at several other sites, and we have established reserves for the currently known sites and for contractual guarantees for environmental liabilities for sites that we have divested. Environmental contingencies arising from certain business divestiture and corresponding retained environmental liabilities are described at Note D.20.1(d) to the consolidated financial statements included in Item 18 of this annual report. More than 30 million have been devoted to clean up expenses in 2004. Some further 400 million have been provisioned to face further expenses. Due to growing costs of compliance with complex environmental regulations accompanied by our internal remediation programs, our provisions for remediation obligations may not be adequate because of the number of factors impacting such estimates: complexity of operating or non-operating sites, nature of claims received, remediation techniques considered, expected horizon for rehabilitation and result of discussions with national regulatory bodies and other potentially responsible parties, at multiparty sites.

We believe that we are not currently subject to liabilities for non-compliance with applicable environmental, health and safety laws and regulations that would materially and adversely affect our business, financial condition or results of operations. We also believe that we are in substantial compliance with environmental, health and safety laws and regulations and that we have obtained all material environmental permits required for the operation of our facilities. We maintain on a regular basis HSE audits in order to detect possible instances of non-compliance and correct them. 23 were carried out in 2004. We are committed to providing safe and environmentally sound work places that will not adversely affect the health or environment of our employees or the communities in which we operate.

We have implemented worldwide a health, safety and environmental policy that promotes the health and well-being of our employees and respect for our environment. We consider this policy to be an integral element of our commitment to social responsibility. The key points of this policy are summarized below.

Table of Contents

Health

From the development of compounds to the launch of new drugs, our research scientists continuously assess the effect of our products on human health. We make this expertise available to our employees through two committees responsible for chemical and biological risk assessment. Our COVALIS committee classifies all chemical and pharmaceutical products handled within the Group and sets workplace exposure limits for each of them. Our TRIBIO Committee classifies all biological agents according to their degree of pathogenicity and establishes guidelines for their containment and the preventive measures to be respected throughout our operations.

Safety

We have a rigorous policy in place to identify and evaluate risks and to develop preventive measures and methods for checking their efficacy. Additionally, we invest in training schemes that are designed to ensure that a concern for safety is built into all professional activities. We implement these policies worldwide to ensure the safety of our employees and to protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures, incorporating the chemical substance and process data, by the COVALIS and TRIBIO committees discussed above. Our preventive measures are designed primarily to reduce the number and seriousness of industrial accidents involving our permanent and temporary employees and the employees of outside contractors.

Our French chemical production sites in Vertolaye, Neuville sur Saône, Saint Aubin-les-Elbeuf, Sisteron and Aramon, as well as our plants located in the Hoechst Industry Park in Frankfurt, Germany, and our chemical production site in Budapest, Hungary are listed Seveso II in accordance with the relevant European directive. In addition, in accordance with the French law on technological risk prevention, our above-mentioned French sites are also subject to heightened security inspections in light of the toxic or flammable materials stored on the sites and used in the operating processes. We believe that the safety management systems implemented at each site, the hazard studies completed and the risk management methods implemented, as well as the insurance policies covering any third-party material damages, are consistent with the legal requirements.

Environment

Our environmental policy's core objectives are to implement clean manufacturing processes, minimize the use of natural resources and reduce the environmental impact of our business. In order to optimize and improve our environmental performance, we are working towards obtaining ISO 14001 certification. Twenty-two manufacturing sites and two R&D sites are certified. Such certification processes are a part of our strategy of continuous improvement that we practice in all of our establishments through the annual implementation of health, safety and environment progress plans. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and environment. As from January 1, 2005, nine of our European sites are part of the European CO₂ emission trading system, which is expected to help to meet the objectives of the Kyoto protocol.

Our recent environmental protection efforts have targeted reduction in energy requirements, improvement in performance of water treatment installations, in the release of volatile organic compounds, savings or recycling of raw materials, and reduction or improved recycled ratios in waste materials. Even with our increased production volume, we have achieved considerable improvements in each of these areas in terms of per produced unit consumption.

Insurance

Prior to their merger, Sanofi-Synthélabo and Aventis each had in place comprehensive global risk financing and insurance programs that provided adequate insurance coverage commensurate with the risk profiles of each company. In late 2004, an agreement was reached with insurers that, effective January 1, 2005, the two companies' insurance programs for major risks would be integrated to provide a single unified risk financing and insurance program for sanofi-aventis providing adequate insurance coverage commensurate with the risk profile of the newly combined company.

This new combined risk and insurance financing program uses a combination of traditional third-party insurance, a multi-company pharmaceutical industry mutual insurance company, and in-house wholly owned captive insurance companies.

Table of Contents

In regard to particular lines of coverage, sanofi-aventis has implemented four types of global coverage, which we believe provides limits and terms equal to or in excess of those considered normal for a global pharmaceutical and vaccine company. Our property and business interruption policies provide 2 billion of limits, and our marine transit policies, including inventory, provide up to 200 million of limits. Our general and product liability, along with our Directors and Officers (D&O) liability policies, also provide limits commensurate with our loss history and risk profile. Further, the global policies that we have put into place cover all subsidiaries and divisions. By centralizing the purchasing of insurance coverage in the major areas of risk, such as products and general liability, property damage and business interruption, and marine transit, we seek to ensure that all insurable catastrophic-type risks are protected and not at risk of being underinsured due to inadequate, locally purchased coverage in some countries.

In regard to products and general liability, sanofi-aventis has structured a risk-financing program to respond to the current, extremely volatile third-party liability insurance market. Third-party insurers have significantly reduced limits available to pharmaceutical companies and placed many restrictions on coverage and product exclusions for health care and pharmaceutical companies. In addition, the third-party insurance market, especially for product liability, in combination with our increased size and risk profile, has made it necessary to increase the attachment point of the third-party insurers on the former Sanofi-Synthélabo risks and retain a significant amount of risk through Carraig Insurance Ltd, our wholly owned captive insurance subsidiary venued and licensed in Ireland.

Despite these challenges, we believe our liability risk financing and insurance program is adequate and commensurate for a company with our risk profile. This is due to combining the capacity of only strongly rated third-party insurers with Carraig. Our third-party liability insurers were rated A or better by Best, the insurance industry rating agency. Our total cost of premiums on all lines combined of third party insurance is less than 0.5% of our consolidated sales.

Animal Health: Merial

Merial, a 50-50 joint venture with Merck & Co. Inc., is one of the world's leading animal healthcare companies dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers and pet owners. The company is also a market leader in the development and production of poultry breeding stock through its subsidiaries Hubbard and British United Turkeys.

The animal healthcare product range comprises four major segments: parasiticides, products for the treatment of chronic illnesses, anti-infectious drugs and vaccines for all commercially important animal species. The company's top-selling products include Frontline®, a topical anti-parasitic flea and tick brand for dogs and cats, as well as Ivomec®, a parasiticide for the control of internal and external parasites in livestock, Heartgard®, a parasiticide for control of heartworm in companion animals, and Eprinex®, a parasiticide for use in cattle.

Merial's major markets are the United States, France, Italy, United Kingdom, Brazil, Australia, Japan, Germany, Spain, and Canada.

The worldwide headquarters and registered office of Merial Ltd are in Harlow (UK). Operational and North American headquarters are based in Duluth, Georgia (U.S.); another important regional office is located in Lyon (France) for Europe, the Middle East and Africa.

Merial has 16 production sites in Europe, North and South America and China, 10 research and development sites worldwide and around 6,000 employees.

Other

Rhodia

As of December 31, 2004, sanofi-aventis held a 15.3% equity stake in the specialty chemicals group Rhodia, which was formerly a unit of Rhône-Poulenc. Rhodia is listed on the Paris stock exchange as well as the New York Stock Exchange since 1998. As a condition for the U.S. and EU antitrust approvals of the business

Table of Contents

combination that created Aventis in 1999, a deadline of April 2004 had been set for Aventis to reduce its 25.2% stake in Rhodia to below 5%. In May 2003, Aventis sold 9.9% of Rhodia's share capital to Credit Lyonnais, reducing its stake to 15.3% (27.5 million shares). Subsequent to this sale, Aventis considered Rhodia a marketable investment and no longer accounted for it using the equity method. On January 30, 2004, the European Commission agreed to replace a commitment obliging Aventis to sell its 15.3% stake in Rhodia with a commitment to divest its 49% stake in Wacker Chemie within a timeframe of several years. In parallel, the U.S. Federal Trade Commission has extended its separate deadline for the disposal of the Rhodia stake by one additional year, until April 22, 2005. We filed a request for a waiver of this obligation in December 2004, and this request is pending.

Wacker Chemie

We indirectly own a 49% equity interest in Wacker Chemie through Hoechst. On December 16, 2000, Hoechst and the Wacker family holding company (*Familiengesellschaft*) entered into a restructuring agreement under which, *inter alia*, Hoechst's share in Wacker-Chemie was reduced from 50% to 49% in a first step, and which provided for a second-step disposal of Hoechst's remaining 49% interest under contractually defined conditions. The second-step disposal did not take place, and Hoechst and the *Familiengesellschaft* are involved in litigation before the Munich regional court (*Landgericht*) concerning the execution of the restructuring agreement.

Yves Rocher

We own a 39% equity interest in Financière des Laboratoires de Cosmétique Yves Rocher.

DyStar

The sale of the shares held by Hoechst AG in DyStar Textilfarben GmbH and DyStar Textilfarben GmbH & Co Deutschland KG, companies engaged in the textile dyes business, to investment vehicles affiliated with Platinum Equities LLC closed on August 4, 2004.

Aventis Behring

The sale of the therapeutic proteins business, Aventis Behring, to CSL Ltd. of Australia was completed on March 31, 2004.

C. Organizational Structure

The table below sets forth our significant subsidiaries and affiliates as of the date of this annual report. For a complete list of our main consolidated subsidiaries, see Note E to our consolidated financial statements, included in this annual report at Item 18.

<u>Significant Subsidiary or Affiliate</u>	<u>Country</u>	<u>Ownership Interest</u>
Aventis Inc.	United States	100%
Aventis Pharmaceuticals Inc.	United States	100%
Loxex Pharmaceuticals Inc.	United States	100%
Sanofi-Synthélabo Inc.	United States	100%
Sanofi-Synthélabo Recherche	France	100%

D. Property, Plant and Equipment

Our worldwide headquarters and principal executive offices are located in Paris, France. Our U.S. headquarters are located in Bridgewater, New Jersey. We operate our business through a number of offices, research facilities and production sites throughout the world. We present our principal sites below by use. All areas are presented in thousands of square meters and are non-audited.

For our pharmaceutical activity, we own and lease space around the world for sales and marketing, administrative support and customer service functions.

Table of Contents

Our Scientific and Medical Affairs are organized across 11 sites located in France and 13 sites located in the rest of Europe, North America and Japan. These sites are either owned or leased. The full list of our sites is as follows:

<u>Country</u>	<u>Appx. Size (thousands of m²)</u>	<u>Location</u>	
France		Antony* (Croix de Berny site)	
		Bagneux	
		Chilly-Mazarin	
		Evry	
		Labège	
		N/A	
		21.7	Montpellier
		63.9	Porcheville
		0.9	
		13.4	Rueil-Malmaison
		52.7	
Germany		25.7	Strasbourg
		11.7	
		7.3	Toulouse
		30.3	
		94.9	Vitry / Alfortville
			Frankfurt*
		N/A	
		19.6	Kastengrund
	United Kingdom	12.6	Alnwick
	Hungary	N/A	Ujpest*
Italy	12.1	Milano	
Spain		Alcobendas*	
		N/A	
		N/A	Riells*
United States		Bridgewater, New Jersey	
		Cambridge, Massachusetts	
		110.8	
		3.2	Malvern, Pennsylvania (Great Valley site)
		30.1	
		1.2	Tucson, Arizona
Japan		Kawagoe*	
		N/A	
	15.7	Tokyo	

* These sites are located within some of our office or industrial sites

Edgar Filing: SANOFI-AVENTIS - Form 20-F

We have a total of 75 sites around the world under the responsibility of our Industrial Affairs division in which we carry out chemical manufacturing, pharmaceutical manufacturing or both. Our principal manufacturing sites are listed below.

<u>Location</u>	<u>Appx. Size (thousands of m²)</u>	<u>Principal Use</u>
France		
Ambarès (P)	72.6	Plavix [®] , Aprovel [®] , Depakine [®]
Amilly (P)	31.1	Other pharmaceutical products
Aramon (C)	51.7	irbesartan
Compiègne (P)	56.0	Other pharmaceutical products
Elbeuf (C)	64.7	Other active ingredients
Le Trait (P)	41.8	Lovenox [®]
Maisons-Alfort (P)	30.6	Lovenox [®]
Neuville sur Saône (C)	73.4	Other active ingredients
Quetigny (P)	28.4	Stilnox [®] , Plavix [®]
Sisteron (C)	58.0	clopidogrel, other active ingredients
Tours (P)	25.6	Stilnox [®] , Aprovel [®] , Xatral [®]
Vertolaye (C)	34.8	Other active ingredients
Vitry (C)	85.3	docetaxel, other active ingredients

Table of Contents

Location	Appx. Size (thousands of m²)	Principal Use	
Germany			
Cologne (P)	46.0	Other pharmaceutical products	
Frankfurt-Biotechnology (C)	}	Bioengineered insulins	
Frankfurt-Chemistry (C)		345.2	fexofenadine, glimepiride, ramipril, telithromycin
Frankfurt (P)		Lantus®, Tritace®	
Italy			
Agnani (P)	41.4	Other pharmaceutical products	
Brindisi (C)	41.7	Other active ingredients	
Gaessio (C)	64.2	Other active ingredients	
Origgio (P)	50.6	Other pharmaceutical products	
Scoppito (P)	29.3	Tritace®, Amaryl®	
United Kingdom			
Dagenham (P)	89.2	Taxotere®	
Fawdon (P)	29.0	Plavix®, Aprovel®	
Holmes Chapel (P)	44.4	Nasacort®, other pharmaceutical products	
Hungary			
Ujpest (C, P)	101.0	irbesartan	
United States			
Kansas City (P)	24.9	Allegra®, Amaryl®	
Japan			
Kawagoe (P)	45.9	Products for local market	
Singapore			
Jurong (C)	40.0	enoxaparin sodium	
India			
Ankleshwar (C, P)	15.0	Products for local market	
Brazil			
Guadalupe (P)	33.4	Products for local market	
Suzano (P)	27.7	Products for local market	
Mexico			
Cuautitlan (P)	32.7	Products for local market	
Ocoyoacac (P)	32.8	Products for local market	
Marocco			
Casablanca (P)	48.0	Products for local market	

Legend: (P) Pharmaceutical Manufacturing, (C) Chemical Manufacturing

For our distribution, we either operate from some of our industrial or R&D sites or from independent sites that we either own or lease. Our major distribution centers located on independent sites are as follows:

Country	Appx. Size (thousands of m²)	Location
France	16.5	Amilly
	21.6	Croissy Beaubourg

Edgar Filing: SANOFI-AVENTIS - Form 20-F

	26.7	Marly la Ville
	15.5	Saint Loubès
United Kingdom	15.4	Sheffield
United States	30.2	Kansas City

Table of Contents

The headquarters of our human vaccines subsidiary sanofi pasteur are located in Lyon, France. Sanofi pasteur has a large industrial operations network with sites located in North America and Europe, as well as in emerging markets such as China, Thailand and Argentina. The location and size of our main manufacturing facilities for human vaccines are as follows:

<u>Location</u>	<u>Appx. Size (thousands of m²)</u>	<u>Principal use</u>
Marcy l Etoile, France	161.7	R&D and bulk production of most of the vaccine active ingredients supplied by sanofi pasteur, also a site for secondary formulation, filling and packaging (FFP)
Val de Reuil, France	50.0	Largest site for FFP, some major active ingredient production (influenza, oral polio vaccine, rabies, yellow fever), worldwide distribution
Swiftwater, Pennsylvania, U.S.	86.4	R&D, production of influenza, meningitis and pediatric combination vaccines, FFP
Toronto, Canada	30.0	R&D, production of pediatric combination vaccines, industrialization of new products

We both own and lease our facilities. We have entered into material leasing and operating leasing agreements with respect to real estate properties located in France in Paris, Amilly, Gentilly, Chilly-Mazarin and Bagneux. Under our operating leases, our real estate properties include buildings constructed pursuant to the operating lease agreements, under which we pay periodic rent and have a purchase option exercisable at expiration. We are responsible for all repairs, taxes and other costs during the term of the operating leases. The operating leases are classified as debt in our consolidated balance sheet.

The overall net book value of our property, plants and equipment was 5,886 million as of December 31, 2004. In 2004, we spent 716 million primarily to increase capacity and improve productivity at our various manufacturing and R&D sites. We believe that our production plants and research facilities are in full compliance, well maintained and generally adequate to meet our needs for the foreseeable future. However, we conduct on a regular basis reviews of our production plants with regard to environment, health and safety issues, quality compliance and capacity utilization. Based on this review, we record, if necessary, impairment losses for the modernization, divestment or closing of specific production plants. We are not aware of any environmental issues that we believe could have a significant effect on the utilization of our industrial assets. For more information on our Property, Plant and Equipment, see Note D.4 to our consolidated financial statements included in Item 18 of this annual report.

Table of Contents**Item 5. Operating and Financial Review and Prospects**

You should read the following discussion in conjunction with our consolidated financial statements and the notes thereto included in this annual report at Item 18. Our consolidated financial statements have been prepared in accordance with French GAAP, which differ in certain significant respects from U.S. GAAP. Note F to our consolidated financial statements provides a description of the principal differences between French GAAP and U.S. GAAP as they relate to our company, and reconciles our shareholders' equity and net income to U.S. GAAP as of, and for each of the years ended, December 31, 2002, 2003 and 2004. Unless otherwise indicated, the following discussion relates to our French GAAP financial information.

The following discussion contains forward-looking statements that involve inherent risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See Item 3. Key Information Risk Factors Cautionary Statement Regarding Forward-Looking Statements.

Introduction

The period from 2002 to 2004 has been one of substantial growth for our company, including external growth resulting from our acquisition of Aventis in August 2004. As a result of the acquisition, our consolidated net sales almost doubled in 2004, increasing from 8,048 million in 2003 to 15,043 million in 2004. We expect a significant additional increase in 2005, as Aventis was only included in our scope of consolidation beginning on August 20, 2004. The pro forma net sales of our two companies in 2004, determined in accordance with the principles described below, amounted to 25,418 million in 2004.

In addition to the acquisition, we have recorded substantial growth in sales of our principal products. Sales of our four leading products prior to our acquisition of Aventis (Plavix[®], Eloxatine[®], Stilnox[®] and Aprovel[®]) increased in 2004 on a comparable basis (adjusting for exchange rate and scope of consolidation differences as described below) over 2003 with double digit growth for each of Plavix[®] (+27.8%), Eloxatine[®] (+48.1%) and Aprovel[®] (+15.7%). The Aventis acquisition has added a number of fast-growing products to our portfolio, including Lovenox[®] (+15.6% in 2004), Taxotere[®] (+5.7%) and Lantus[®] (+69.3%).

Our operating profit and net income were impacted in 2004 by the accounting treatment of the Aventis acquisition, which led to our recording the inventory of Aventis at fair value rather than historical cost, leaving us with significantly reduced margins when we sold the inventory, and which required us to record an expense equal to the value of the Aventis research and development in progress at the time of the acquisition. Because of the effect of these two items (which respectively amounted to 343 million in after tax charges and 5,045 million without any tax impact in 2004) as well as the amortization of goodwill and acquired intangible assets and restructuring charges arising from the acquisition, we recorded an operating loss of 305 million and a net loss of 3,610 million in 2004, compared to operating income of 3,075 million and net income of 2,076 million in 2003. Without the effect of these charges, our adjusted net income in 2004 amounted to 3,565 million. Adjusted net income is a non-GAAP financial measure which our management uses to monitor our operational performance, and which is defined at Sources of Revenues and Expenses Adjusted net income, below.

Our operations generate significant cash flow. We recorded 2,265 million of net cash flow from operating activities in 2003 and 4,029 million in 2004 (including in 2004 the net cash flow from the operating activities of Aventis beginning August 20, 2004). Until the acquisition, we typically maintained cash and cash equivalents in amounts that exceeded our debt. We incurred significant debt to finance the acquisition, a portion of which we have refinanced. As of December 31, 2004, our consolidated net debt (meaning debt less cash and cash equivalents and short term investments excluding treasury shares held in connection with stock option plans) was 14,160 million.

Impact of our Acquisition of Aventis

Our results of operations and financial condition as of and for the year ended December 31, 2004 have been significantly impacted by our August 2004 acquisition of Aventis and certain subsequent transactions (including the merger of Aventis with and into our company in December 2004). The principal impacts of these transactions on our 2004 consolidated financial statements and their comparability to those of prior periods are the following:

The results of operations of Aventis for the period between August 20, 2004 and December 31, 2004 have been included in our consolidated statement of income and consolidated statement of cash flows.

Table of Contents

This resulted in a significant increase in net sales and significant changes in other financial statement items in 2004 compared to 2003. The assets and liabilities of Aventis are also included in our consolidated balance sheet as of December 31, 2004.

The composition of our top selling products has changed significantly compared to that of our company prior to the acquisition. As a result, our 2004 revenues are derived in part from a different product base compared to our 2003 revenues.

We incurred an operating loss in 2004 as a result of two aspects of the accounting treatment relating to the acquisition:

the allocation of a portion of the purchase price to inventory at fair value, which resulted in our recording a sharply reduced gross margin when we sold the inventory (342 million after tax), and

the expensing of acquired research and development (5,046 million).

We divested certain assets in connection with the acquisition, including two products, Fraxiparine® and Arixtra®, that we sold in order to respond to potential demands from competition authorities in relation to the acquisition. Aventis also divested certain assets, notably its product Campto®.

We issued 678.6 million new shares in the offers and subsequent merger representing about 48% of our issued share capital as of December 31, 2004, and incurred significant indebtedness in connection with the acquisition. As a result, our consolidated net debt stood at 14,160 million on December 31, 2004 against a net cash position of 2,397 million on December 31, 2003.

We have prepared an unaudited pro forma statement of income for 2004 that presents our results of operations as if the acquisition had taken place on January 1, 2004. In accordance with French regulatory requirements, we have also prepared a comparative unaudited pro forma statement of income for 2003. The comparative unaudited pro forma statement of income presents our results of operations as if the acquisition had taken place on January 1, 2003. For a detailed description of the principles used to establish the pro forma financial statements, see Note D.1, section 5, to the consolidated financial statements included in Item 18. Financial Statements in this report.

The unaudited pro forma financial data are presented for illustrative purposes only and are not necessarily indicative of the operating results or financial condition of the combined entities that would have been achieved had the transactions been consummated on the dates used as the basis for the preparation of the pro forma financial data. They are not necessarily indicative of the future results or financial condition of sanofi-aventis.

Nonetheless, because the unaudited pro forma income statements provide information that we believe is useful in analyzing trends in our business, we have discussed our pro forma results of operations, as well as our historical results of operations, in the comparisons of the years 2003 and 2004 below.

The following table presents our net sales, operating income and net income in 2003 and 2004, on both a consolidated and pro forma basis.

Consolidated	Pro Forma (unaudited)
Year ended December 31,	Year ended December 31,

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>In millions of euros</i>	2003	2004	2003	2004
Net Sales	8,048	15,043	24,296	25,418
Operating Profit/(Loss)	3,075	(305)	7,254	8,163
Net Income/(Loss)	2,076	(3,610)	977	1,706

As discussed above, the accounting treatment of the acquisition had a significant impact on our consolidated income statement in 2004. In addition to the impact of the allocation of a portion of the purchase price to inventory at fair value and of expensing acquired research and development, the acquisition gave rise to significant amortization charges for goodwill and acquired intangible assets (goodwill and acquired intangible assets are amortized on a periodic basis under French GAAP). Similar impacts were recorded in respect of companies accounted for by the equity method. In addition, we recorded significant restructuring charges as a result of the acquisition.

Table of Contents

In order to isolate the impact of these items, we use as an evaluation tool a non-GAAP financial measure that we refer to as Adjusted Net Income. For a further discussion and definition of Adjusted Net Income, see Sources of Revenues and Expenses Adjusted Net Income, below.

We have calculated the adjusted consolidated net income of sanofi-aventis for 2004, as it is the only year in which the relevant items had an impact on our consolidated net income. We have also calculated adjusted pro forma net income for 2003 and 2004, based on the same principles but starting with our unaudited pro forma net income. The following table shows our adjusted consolidated net income for 2004 and our adjusted pro forma net income for 2003 and 2004, in each case including a reconciliation to consolidated net income or pro forma net income, as the case may be.

	Year ended December 31,		
	2004	2003	2004
<i>In millions of euros, except per share data</i>			
	(consolidated)	(pro forma, unaudited)	
Net Income / (Loss)	(3,610)	977	1,706
<i>Adjustments:</i>			
Elimination of expensing of acquired research and development in progress	5,046		
Elimination of charges arising from accounting for acquired inventory at fair value, net of tax	342		
Elimination of amortization expense on goodwill generated by the acquisition of Aventis	283	856	817
Elimination of expenses arising on amortization of Aventis intangible assets, net of tax and minority interests	786	2,530	2,274
Elimination of expenses arising from the impact of the acquisition of Aventis on equity affiliates (acquired research, inventory accounted for at fair value, amortization of goodwill and intangible assets)	356	88	88
<i>Elimination of restructuring charges, net of tax</i>	362		362
Adjusted net income	3,565	4,451	5,247
Adjusted net income per share	3.86(1)	3.29(2)	3.89(2)

- (1) Based on 923,286,539 shares, equal to the weighted average number of shares outstanding in 2004 for consolidated net income.
- (2) Based on 1,352,146,319 shares (for 2003) and 1,347,480,482 shares (for 2004), equal to the weighted average number of shares outstanding in each of those years, determined as if the acquisition had taken place on January 1, 2003 (for the 2003 figures) or January 1, 2004 (for the 2004 figures).

Sources of Revenues and Expenses

Revenues. Our principal source of revenues is the sale of pharmaceutical products and human vaccines. We sell these products directly, through alliances and through licensees throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the overall level of sales of the products and on the arrangements governing those alliances. For more information about our alliances, see Financial Presentation of Alliances below. When we sell products through licensees, we receive royalty income that we record as a reduction in our cost of goods sold, as discussed further below.

Cost of Goods Sold. Our cost of goods sold consists primarily of the cost of purchasing active ingredients and raw materials, labor and other costs relating to our manufacturing activities, packaging materials and distribution costs, as well as government levies that we are required to pay in some countries.

Our cost of goods sold also includes our net royalties relating to license agreements for products. We have license agreements under which we distribute products that are patented by other companies and license agreements under which other companies distribute products that we have patented. When we pay royalties, we record them in cost of goods sold, and when we receive royalties, we record them as reductions in our cost of goods sold.

Table of Contents

Operating Profit/(Loss). Our operating profit (or loss) consists of gross profit less research and development expenses, selling and general expenses and items that we record as other operating income/(expense), net. We expense all of our research and development costs as incurred. Our other operating income/(expense), net relates primarily to profit sharing arrangements with partners under joint ventures and alliance agreements for the marketing of products. The effects of these profit sharing arrangements are reflected in operating profit. See Financial Presentation of Alliances below for a description of these arrangements. Amortization and impairment of intangible assets is presented below operating profit in our consolidated financial statements.

Adjusted Net Income. We believe that investors' understanding of our operational performance following the combination of Sanofi-Synthélabo and Aventis is enhanced by disclosing our adjusted net income.

We define adjusted net income, a non-GAAP financial measure, as net income determined under French GAAP, adjusted to exclude the material impacts of purchase accounting for the Aventis acquisition and certain acquisition-related integration and restructuring costs. We view adjusted net income as an operating performance measure and believe that the most directly comparable French GAAP measure is net income.

Adjusted net income excludes the effects of purchase-accounting treatment under French GAAP related to our acquisition of Aventis. We believe that excluding these non-cash charges will enhance an investor's understanding of our underlying economic performance after the combination with Aventis because we do not consider that the excluded charges reflect the combined entity's ongoing operating performance. Rather, we consider that each of the excluded charges reflects the decision, in 2004, to acquire the businesses of Aventis. The purchase-accounting effects on net income primarily relate to:

the one-time expensing of acquired research and development in progress;

the charges to cost of goods sold resulting from the workdown of acquired inventory that was written up to fair value, net of tax;

the charges related to the amortization of the goodwill arising from the acquisition of Aventis;

the charges related to the amortization of Aventis's definite-lived intangible assets, net of tax and minority interests.

In the pro forma statements of income for the years ended December 31, 2003 and December 31, 2004, the differences between adjusted net income and net income are due mainly to the effects of the revaluation of assets and liabilities at fair value.

We also believe (subject to the material limitations discussed below) that disclosing adjusted net income will also enhance the comparability of our ongoing operating performance. The elimination of the non-recurring items (the one-time charge for acquired research and development in progress and the charges to cost of goods sold resulting from the workdown of acquired inventory that was written up to fair value) will enhance comparability after the combination from one period to the other. The elimination of the amortization of goodwill resulting from the acquisition of Aventis will also enhance comparability (1) across periods after the combination (because starting in 2005, we are required to publish our financial statements under International Financial Reporting Standards, or IFRS, under which goodwill is not amortized; for a description of IFRS, see Exhibit 99.2 of this annual report) and (2) relative to our peers in the pharmaceutical industry (many of which, including Eli Lilly, Johnson & Johnson, Pfizer, Bristol Myers Squibb, Abbott, Wyeth, Merck & Co. and Schering Plough, report their results under U.S. GAAP, under which accounting principles goodwill is not amortized). Lastly, we believe that the elimination of charges related to the amortization of Aventis's definite-lived intangible assets will also enhance the comparability of our ongoing operating performance relative to our peers in the

Edgar Filing: SANOFI-AVENTIS - Form 20-F

pharmaceutical industry that carry these intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted as poolings-of-interest.

As a result of the acquisition, we have incurred and will incur significant integration and restructuring costs. We believe it appropriate to exclude these costs from adjusted net income because these integration and restructuring costs are and will be directly and only incurred in connection with the acquisition of Aventis, and we reasonably believe that these costs will disappear or become immaterial within eighteen months of the acquisition. We currently expect to have incurred substantially all of the integration and restructuring costs by the

Table of Contents

end of 2005. The costs will occur over an eighteen-month period because of the unusual complexity and size of the global business combination and the highly regulated nature of our operations. It is not our business or past practice to restructure on a continuous basis. Prior to our acquisition of Aventis, the last material integration and restructuring costs we incurred arose out of the May 1999 merger between Sanofi and Synthélabo and were substantially expensed by the end of 2001, in accordance with the expectations of management at the time of that merger.

Our management uses and intends to use adjusted net income to manage and to evaluate our performance and we believe it is appropriate to disclose this non-GAAP financial measure, as a supplement to our French GAAP reporting, to assist investors with their analysis of the factors and trends affecting our business performance. We also report adjusted net income as a subtotal in reporting our segment information in accordance with SFAS 131 criteria. See Note D.29 to the Consolidated Financial Statements included in Item 18 of this annual report. Our management also uses the measure as a component in setting incentive compensation targets, because it better measures the underlying operational performance of the business and excludes charges over which managers have no control. Our management also uses adjusted net income as the basis for determining dividend policy for the combined Group, by analyzing dividends paid as a ratio of non-GAAP adjusted net income, which management believes provides a consistent basis for comparison across periods. Accordingly, management believes that an investor's understanding of the evolution of our dividend policy is enhanced by disclosing non-GAAP adjusted net income.

We have also decided to report adjusted earnings per share (EPS). Adjusted earnings per share is a specific financial indicator, which we define as adjusted net income divided by the weighted average number of shares outstanding. Our management also intends to give earnings guidance based on adjusted earnings per share.

We remind investors, however, that non-GAAP adjusted net income should not be considered in isolation from, or as a substitute for, net income reported in accordance with French GAAP. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, and our other publicly-filed reports carefully and in their entirety.

There are material limitations associated with the use of non-GAAP adjusted net income as compared to the use of French GAAP net income in evaluating our performance, as described below:

The results presented by non-GAAP adjusted net income cannot be achieved without incurring the following costs that the measure excludes:

Amortization of identifiable intangible assets acquired from Aventis. Although this amortization is a non-cash charge, it is important for investors to consider it because it represents an allocation in each reporting period of a portion of the purchase price that we paid for the identifiable intangible assets of Aventis (principally patents and trademarks). We paid an aggregate of 32,090 million for these intangible assets (which, in general, will be amortized over their useful lives ranging from 7 to 17 years). A large part of our revenues after the combination could not be generated without owning these assets. Also, a significant portion of the purchase price paid for these assets has been financed by debt obligations which will need to be repaid in cash in the future. Further, if we do not continuously replace revenue-generating intangible assets as they become unproductive (for example, through researching and developing new pharmaceutical products), we may not be able to maintain or grow our revenues.

Integration and restructuring costs. Non-GAAP adjusted net income does not reflect any integration and restructuring costs even though it reflects any synergies that arise from the combination of Sanofi-Aventis and Aventis.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

The difference in treatment of similar charges may complicate the use of non-GAAP adjusted net income as a comparative measure:

Amortization of identifiable intangible assets. Non-GAAP adjusted net income reflects amortization charges related to intangible assets that we owned at the time that we acquired Aventis (and to intangible assets that it may acquire after that acquisition), even though non-GAAP adjusted net income will not reflect the amortization charges related to identifiable intangible assets acquired from Aventis.

Table of Contents

Amortization of Goodwill. Non-GAAP adjusted net income will reflect the amortization of goodwill that we had recorded on our accounts at the time that we acquired Aventis (and the amortization of goodwill that sanofi-aventis may acquire after that acquisition), even though non-GAAP adjusted net income excludes the amortization of goodwill that arose as a result of the acquisition of Aventis.

We compensate for the above described material limitations by using non-GAAP adjusted net income only to supplement our French GAAP financial reporting (and any reconciliation of French GAAP results to U.S. GAAP that we are required to make under the rules of the U.S. SEC) and by ensuring that our disclosures provide sufficient information for a full understanding of all adjustments included in non-GAAP adjusted net income. In addition, subject to applicable law, we may in the future decide to report additional non-GAAP financial measures which, in combination with non-GAAP adjusted net income, may compensate further for some of the material limitations described above.

In determining the level of future dividend payments, and in analyzing dividend policy on the basis of non-GAAP adjusted net income, our management intends to take into account the fact that a significant portion (approximately 10.5 billion) of the purchase price we paid for Aventis (including the purchase price allocated to identifiable intangible assets and goodwill) has been financed with borrowed funds and that this borrowed money will have to be repaid in cash in the medium term. See Consolidated Balance Sheet and Debt, below. Further, our management intends to take into account the fact that the adjustments reflected in non-GAAP adjusted net income have no effect on the underlying amount of cash available to pay dividends, and that although the adjustments relating to the elimination of the effect of the purchase accounting treatment of the Aventis acquisition represent non-cash charges, the adjustments relating to integration and restructuring costs represent significant cash charges in the periods immediately following the closing of the acquisition.

This Item 5 contains discussion and analysis of adjusted net income on the basis of both consolidated and pro forma financial data. Because our non-GAAP adjusted net income is not a standardized measure, it may not be comparable with the non-GAAP financial measures of other companies having the same or a similar name.

Treatment of Milestone Payments Under Licensing Agreements

When we enter into a licensing agreement with respect to products under development, we frequently pay the patent owner an up-front payment and/or payments for reaching certain development milestones. If the product has not yet received regulatory approval, we record these payments as additions to our research and development expenses. If the product has already received regulatory approval or the payment is made upon receipt of regulatory approval, we record the payment as an addition to our intangible assets, which is amortized over the shorter of the useful life of the product and the duration of the relevant license.

Presentation of Net Sales

In the discussion below, we present our consolidated and pro forma net sales for each period, and we break down our net sales among various categories, such as by activity, product and geographical area. We refer to our consolidated and pro forma sales as reported sales.

Consolidated Net Sales. For 2004, our consolidated net sales include the net sales of Aventis and its subsidiaries from August 20, 2004. For the years ended December 31, 2002 and December 31, 2003, our consolidated net sales comprise the consolidated net sales of Sanofi-Synthélabo for these years.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Pro forma Net Sales. Pro forma net sales comprise consolidated net sales as reported by sanofi-aventis, plus Aventis net sales over twelve months for the year ended December 31, 2003 and over the period from January 1 to August 20 for the year ended December 31, 2004, excluding net sales of Arixtra[®], Fraxiparine[®] and Campto[®] (divested at the request of the antitrust authorities, and eliminated from the start of the periods presented), and excluding the Aventis Behring business which was divested in March 2004. The derivation of our condensed pro forma financial results is set out at Note D.1 to our consolidated financial statements included in Item 18 of this annual report.

Table of Contents

In addition to reported sales, we also present and discuss two other non-GAAP indicators that we believe are useful measurement tools to explain changes in our reported net sales:

Comparable Sales. When we refer to the change in our net sales on a comparable basis, we mean that we exclude the impact of exchange rate fluctuations and changes in our group structure (due to acquisitions and divestitures of entities, rights to products and changes in the consolidation percentage for consolidated entities). For any two periods, we exclude the impact of exchange rates by recalculating net sales for the earlier period on the basis of exchange rates used in the later period. We exclude the impact of acquisitions by including sales for a portion of the prior period equal to the portion of the current period during which we owned the entity or product rights based on sales information we receive from the party from whom we make the acquisition. Similarly, we exclude sales in the relevant portion of the prior period when we have sold an entity or rights to a product. If there is a change in the consolidation percentage of a consolidated entity, the prior period is recalculated on the basis of the consolidation method used for the current period.

Because of the significance of the impact of the Aventis acquisition, we present our comparable-basis sales for 2004 on a pro forma basis (reflecting the principles discussed above that we used to prepare our pro forma financial data). We believe this is useful because it allows us to exclude from the comparable-basis presentation the impact of exchange rates on sales of Aventis products and of changes in the scope of consolidation at Aventis.

A reconciliation of our reported pro forma net sales to our pro forma comparable-basis net sales is provided below in the unaudited pro forma results of operations section comparing 2003 to 2004, and a reconciliation of our reported consolidated net sales to our consolidated comparable-basis net sales is provided below in the results of operations section comparing 2002 to 2003.

Developed Sales. When we refer to developed sales of a product, we mean sales consolidated by sanofi-aventis, excluding sales of products to our alliance partners, but including sales not consolidated by sanofi-aventis and made through the alliances with Bristol-Myers Squibb (as described under Financial Presentation of Alliances below) on Plavix® (clopidogrel) and Aprovel® (irbesartan) and with Fujisawa on Stilnox® (zolpidem). Our alliance partners provide us with information about their sales in order to allow us to calculate developed sales. We believe that developed sales are a useful measurement tool because they demonstrate trends in the overall presence of our products in the market. Only products originating from sanofi-aventis research and development are included in alliance partner sales for the purposes of calculating developed sales.

As is the case for comparable basis sales, we present our developed sales on a pro forma basis, given the significance of the Aventis acquisition. We believe this presentation demonstrates trends in the overall presence of sanofi-aventis products in the worldwide market without regard to the date of acquisition.

A reconciliation of our pro forma developed sales to our pro forma net sales is provided below in the unaudited pro forma results of operations section comparing 2003 to 2004, and a reconciliation of our historical developed sales to our historical consolidated net sales is provided below in the results of operations section comparing 2002 to 2003.

Financial Presentation of Alliances

We have entered into a number of alliances for the development, co-promotion and/or co-marketing of our products. We believe that a presentation of our two principal alliances is useful to an understanding of our financial statements.

BMS Alliance

Our revenues, expenses and operating profits are affected significantly by the presentation of our alliance with Bristol-Myers Squibb (BMS) in our consolidated financial statements.

The two products that are subject to the BMS alliance, Aprovel[®] and Plavix[®], accounted for an aggregate of 1,549 million of consolidated net sales in 2002, 2,008 million of consolidated net sales in 2003 and 2,484 million of consolidated net sales in 2004. Total developed sales of the two products amounted to an aggregate of 3,655 million in 2002, 4,480 million in 2003 and 5,557 million in 2004.

Table of Contents

The proportion of developed sales of these products represented by our consolidated revenues from these products varies from year to year because differences in the marketing arrangements for these products from country to country impact the presentation of sales of these products. There are three principal marketing arrangements that are used:

Co-marketing. Under the co-marketing system, each company markets the products independently under its own brand names. We record our own sales and related costs in our consolidated financial statements.

Exclusive Marketing. Under the exclusive marketing system, one company has the exclusive right to market the products. We record our own sales and related costs in our consolidated financial statements.

Co-promotion. Under the co-promotion system, the products are marketed through the alliance arrangements (either by contractual arrangements or by separate entities) under a single brand name. The accounting treatment of the co-promotion arrangement depends upon who has majority ownership and operational management in that territory, as discussed below.

The alliance arrangements include two royalty streams that are applied on a worldwide basis (excluding Japan), regardless of the marketing system and regardless of which company has majority ownership and operational management:

Discovery Royalty. We earn a discovery royalty on all sales of Aprovel[®] and Plavix[®] regardless of the marketing system. The discovery royalty is reflected in our consolidated statement of income in our gross profit, which results in an increase in our gross margin.

Development Royalty. In addition to the discovery royalty, we and BMS are each entitled to a development royalty related to certain know-how and other intellectual property in connection with sales of Aprovel[®] and Plavix[®]. Each legal entity that markets products pays a development royalty. We record development royalties paid to BMS in our consolidated statement of income as an increase to our cost of goods sold in countries where we consolidate sales of the products. We record development royalties that we receive as a reduction to our cost of goods sold in countries where BMS consolidates sales of the products.

In 2004, we received an aggregate of 650 million in royalties under the alliance arrangements, and we paid BMS an aggregate of 63 million in royalties under the alliance arrangements (compared to 501 million and 51 million, respectively, in 2003).

Under the alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world excluding Japan. In Japan, Aprovel[®] is under development through agreements between BMS and the Japanese pharmaceutical company Shionogi Pharmaceuticals, and Plavix[®] is under development through an alliance between our company and Daiichi Pharmaceuticals Co., Ltd.

Territory under our operational management. In the territory under our operational management, the marketing arrangements are as follows:

We use the co-promotion system for most of the countries of Western Europe for Aprovel[®] and Plavix[®] and for certain Asian countries for Plavix[®]. We record 100% of all alliance revenues and expenses in our consolidated financial statements. We also record, as selling and general expenses, payments to BMS for the cost of BMS's personnel involved in the promotion of the products.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

BMS's share of the operating profit of the alliances is recorded as other operating income/(expense), net and thus is deducted from our operating profit.

We use the co-marketing system in Germany, Spain and Greece for both Aprovel® and Plavix® and in Italy for Aprovel®.

We have the exclusive right to market Aprovel® and Plavix® in Eastern Europe, Africa and the Middle East, and we have the exclusive right to market Aprovel® in Asia (excluding Japan).

Table of Contents

Territory under BMS operational management. In the territory under BMS operational management, the marketing arrangements are as follows:

We use the co-promotion system in the United States and Canada, where the products are sold through the alliances under the operational management of BMS. There are different arrangements applicable to each of the two products in these countries:

Aprovel[®]. With respect to Avapro[®] (the brand name used in the United States for Aprovel[®]), in October 2001, we entered into an agreement to increase our participation in the promotional activities and profitability of Aprovel[®] in the United States and we have made payments to BMS totalling \$350 million under this agreement. In addition to our profit share recorded under other operating income/(expense), net, we also receive payments from BMS for the cost incurred for our personnel in connection with the promotion of the product (which are deducted from our consolidated selling and general expenses).

Plavix[®]. With respect to Plavix[®], we record our share of the alliance's operating profit under other operating income/(expense), net, with the result that our operating profit is increased by this amount. We also record payments from BMS for the cost of our personnel in connection with the promotion of the product as a deduction from our selling and general expenses.

We use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix[®] and Aprovel[®] and in Colombia for Plavix[®].

We have the exclusive right to market the products in certain other countries of Latin America.

In countries where the products are marketed by BMS on a co-marketing basis, or through alliances under the operational management of BMS, we also earn revenues from the sale of the active ingredients for the products, which we record as net sales in our consolidated statement of income.

P&G Alliance

The other principal alliance with a significant effect on our revenues, expenses and operating profits is our alliance with Procter & Gamble Pharmaceuticals (P&G) relating to the product Actonel[®] (risedronate sodium). Actonel[®], a new-generation biphosphonate indicated for the treatment and prevention of osteoporosis, is developed and marketed in collaboration with P&G under an agreement signed in April 1997 and amended on October 8, 2004. This agreement covers the worldwide development and marketing of the product except for Japan, which is not included in the alliance and is covered by a separate marketing agreement.

Under the Actonel[®] alliance, local marketing arrangements may take various forms:

Co-promotion, whereby sales resources are pooled but only one of the two partners invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. As of December 31, 2004, P&G sells the product and incurs all the related costs for the following countries: United States of America, Canada, France, Germany, Belgium, the Netherlands and Luxembourg. We recognize our share of revenues under the agreement in the statement of income on the line Other operating income/(expense), net. In the United Kingdom and Ireland, we sell the product, and recognize all the revenues from sales of the product along with the corresponding expenses in our consolidated statement of income.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Co-marketing, which applies only in Italy, whereby each partner sells the product in the country under its own name, and recognizes all revenues and expenses from its own operations in its statement of income.

In all other territories, we have exclusive rights to sell the product. We recognize all revenues and expenses from our own operations in our statement of income, but in return for these exclusive rights pay P&G a royalty based on actual sales. This royalty is recognized in cost of goods sold.

Impact of Exchange Rates

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly

Table of Contents

impacted by exchange rate movements between the euro and other currencies, primarily the U.S. dollar, the British pound, the Japanese yen and, to a lesser extent, currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2004, we earned 34.5% of our pro forma net sales in the United States. A decrease in the value of the U.S. dollar against the euro, like that experienced during 2003 and 2004, has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively impacts our operating profits. A decrease in the value of the U.S. dollar has a particularly significant impact on our operating margins, which are higher in the United States than elsewhere due mainly to the fact that we record operating profit, but only limited consolidated net sales, from sales of Plavix® and Aprovei® in the United States by alliance entities under the operational management of BMS.

As a general policy, we do not specifically hedge foreign currency net investments, but rather engage in various foreign currency transactions to reduce our exposure to the risks arising from fluctuations in exchange rates and to protect our operating margins. Hedging instruments relate to assets and liabilities existing at the balance sheet date and, in some cases, to commitments related to future transactions as determined in our annual forecast process.

Divestments

In connection with our acquisition of Aventis, and to comply with the demands of the U.S. and European antitrust authorities, we sold our worldwide rights in respect of two products, Arixtra® and Fraxiparine®, and related assets including the manufacturing facility at Notre-Dame de Bondeville in France, to the GlaxoSmithKline group (GSK). The contract price was 453 million, subject to adjustment, and the sale was conditional upon completion of our offers for Aventis. The sale was completed on September 1, 2004.

In addition, in response to requests made by the antitrust authorities, Aventis sold its interest in the product Campto® (irinotecan) to Pfizer for a maximum price of \$620 million including milestone payments based on registration of new future indications. Pfizer took over key clinical studies for Campto® that were being conducted by Aventis, together with certain patents and other assets relating to territories where Pfizer was marketing irinotecan, including the United States. In a second phase, Pfizer acquired all the other assets relating to Campto® held by Aventis. The sale was completed on October 1, 2004.

In addition to these divestments, Aventis sold its interest in its subsidiary Aventis Behring. Because the sale took place before our acquisition of Aventis, the sale had no impact on our consolidated financial statements. In addition, in the preparation of our pro forma statements of income, the results of operations of Aventis Behring have been excluded from those of Aventis. See Note D.1, point 5, to our consolidated financial statements included in Item 18. Financial Statements in this report.

Results of Operations

Sales of top 15 products

As noted above, one important impact of the Aventis acquisition was to change the composition of our top selling pharmaceutical products, which account for the bulk of our consolidated net sales. Our top 15 products accounted for 60.5% of our pro forma net sales for the pharmaceuticals activity in 2004.

Table of Contents

Because 9 of our top 15 products are products acquired with Aventis, trends with respect to the sales of these products are not fully reflected in our consolidated financial statements for 2004, and are not reflected at all in our consolidated financial statements for 2002 or 2003. The following table shows total sales of our current top 15 products in 2003 and 2004, indicating which products have always been our products (an S appears in parentheses after the product name) and which are former Aventis products (an A appears in parentheses after the product name).

<i>In millions of euros</i>		2003	2004	Change (%)
Product	Indication	pro forma reported	pro forma	2003/2004
Lovenox® (A)	Thrombosis	1,647	1,904	+15.6%
Plavix® (S)	Atherothrombosis	1,325	1,694	+27.8%
Allegra® (A)	Allergic rhinitis	1,740	1,502	-13.7%
Taxotere® (A)	Breast cancer, lung cancer, prostate cancer	1,359	1,436	+5.7%
Stilnox® (S)	Insomnia	1,345	1,423	+5.8%
Eloxatine® (S)	Colorectal cancer	824	1,220	+48.1%
Delix®/Tritace® (A)	Hypertension	1,182	972	-17.8%
Lantus® (A)	Diabetes	498	843	+69.3%
Aprovel® (S)	Hypertension	683	790	+15.7%
Copaxone® (A)	Multiple sclerosis	620	742	+19.7%
Amaryl® (A)	Diabetes	600	684	+14.0%
Actonel® (A)	Osteoporosis, Paget's disease	194	305	+57.2%
Depakine® (S)	Epilepsy	277	303	+9.4%
Nasacort® (A)	Allergic rhinitis	278	287	+3.2%
Xatral® (S)	Benign prostatic hyperplasia	222	281	+26.6%

Year ended December 31, 2004 compared with year ended December 31, 2003

Consolidated Results of Operations*Consolidated net sales*

We had total consolidated net sales of 15,043 million in 2004, representing an increase of 86.9% over net sales of 8,048 million in 2003. The magnitude of the difference was the result of the consolidation of the net sales of Aventis beginning on August 20, 2004.

Our consolidated net sales are generated by our two main businesses: our pharmaceuticals activity and our human vaccines activity. The following table breaks down our 2004 and 2003 consolidated net sales by activity:

<i>In millions of euros</i>	2003	2004	Change (%)
	reported	reported	reported
Pharmaceuticals	8,048	14,360	+78.4%
Human vaccines	0	683	

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Total	8,048	15,043	+86.9%
--------------	--------------	---------------	---------------

We divide our sales into three markets: Europe, the United States and other countries. The following table breaks down our 2004 and 2003 consolidated net sales by market:

<i>In millions of euros</i>	2003	2004	Change (%)
	reported	reported	reported
Europe			
United States	4,693	7,351	+56.6%
Other countries	1,912	4,658	+143.6%
Total	8,048	15,043	+86.9%

In Europe, we had consolidated net sales of 7,351 million in 2004, representing 48.8% of total consolidated net sales in 2004, compared to 58.3% in 2003.

Table of Contents

In the United States, our consolidated net sales reached 4,658 million in 2004, representing 31.0% of total consolidated net sales in 2004, compared to 23.8% in 2003, reflecting the greater relative presence of Aventis in the United States compared to sanofi-aventis prior to the acquisition.

In other countries, our consolidated net sales reached 3,034 million in 2004, representing 20.2% of total consolidated net sales, compared to 17.9% in 2003.

Consolidated gross profit

Our consolidated gross profit was 11,290 million in 2004, compared to 6,620 million in 2003, and represented 75.1% of consolidated net sales in 2004, compared to 82.3% in 2003. This decrease in gross margin was mainly due to an increase of 539 million in the cost of goods sold (before tax), reflecting the accounting treatment of the Aventis acquisition which led us to record the inventory of Aventis at fair value rather than historical cost, leaving us with significantly reduced margins when we sold part of this inventory in 2004.

Consolidated operating loss

Our consolidated operating loss was 305 million in 2004, compared to a consolidated operating profit of 3,075 million in 2003. This change was due mainly to the accounting treatment of the Aventis acquisition, which impacted cost of goods sold as described above and our research and development expenses as described below.

The following table breaks down our operating profit for 2004 and 2003 among its principal components:

<i>In millions of euros</i>	2003		2004	
		As % of net sales		As % of net sales
Net sales	8,048	100.0%	15,043	100.0%
Cost of goods sold	(1,428)	(17.7%)	(3,753)	(24.9%)
Gross profit	6,620	82.3%	11,290	75.1%
Research and development expenses	(1,316)	(16.4%)	(7,455)	(49.6%)
Selling and general expenses	(2,477)	(30.8%)	(4,500)	(29.9%)
Other operating income/(expense), net	248	3.1%	360	2.4%
Operating profit	3,075	38.2%	(305)	(2.0%)

Research and development expenses increased to 7,455 million in 2004, compared to 1,316 million in 2003, and represented 49.6% of consolidated net sales in 2004, compared to 16.4% in 2003. This increase was due in particular to the accounting treatment of the Aventis acquisition, which required us to record an expense equal to the value of the Aventis research and development in progress at the time of the acquisition (5,046 million) and to the inclusion of Aventis research and development expenses from August 20, 2004.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

For additional information regarding our R&D activities, please see Item 4. Information on the Company Business Overview Research and Development.

Selling and general expenses were 4,500 million in 2004 compared to 2,477 million in 2003. This increase was mainly due to the inclusion of Aventis selling and general expenses from August 20, 2004.

Our other operating income/(expense), net was 360 million in 2004, compared to 248 million in 2003. As discussed above, this item reflects operating profits of our alliances (mainly, Bristol-Myers Squibb, and in 2004, Procter & Gamble Pharmaceuticals, Altana, Fujisawa, Sankyo and Teva) to which we are entitled or to which our partners are entitled. In 2004, our profit share from sales of Plavix® and Aprovel® by alliance entities under the operational management of BMS, mainly in North America, were 581 million, compared to 436 million in 2003. We paid to BMS profit shares relating to sales of these products by alliance entities under our operational management in the amount of 257 million euros in 2004, compared to 173 million in 2003.

Table of Contents

Amortization and impairment of intangibles

Our amortization and impairment of intangible assets was 1,563 million in 2004, compared to 129 million in 2003, including 1,442 million arising from the amortization of intangible assets acquired on the acquisition of Aventis from August 20, 2004 and 11 million on Arixtra® and Fraxiparine® over the first eight months of the year.

Consolidated net financial income/(expense)

Consolidated net financial income decreased from 155 million in 2003 to 25 million in 2004. This reduction was due mainly to the cost of our increased debt resulting from the financing the acquisition of Aventis.

Exceptional items

We recorded a net exceptional loss of 402 million in 2004, compared to net exceptional income of 24 million in 2003. The loss in 2004 includes restructuring charges of 557 million arising from the acquisition of Aventis.

Income taxes

Income taxes decreased to 819 million in 2004 from 1,058 million in 2003. Our effective tax rate in 2004 and 2003 are not comparable because of the consolidated net loss recorded in 2004 and because of the business combination with Aventis. For tax purposes the accounting expense equal to the value of the Aventis research and development in progress at the time of the acquisition (5,046 million) is not recognized as an expense in the calculation of taxable income. For additional information on our income taxes in 2004, see Year Ended December 31, 2004 compared with year ended December 31, 2003 Unaudited Pro Forma Results of Operations Pro Forma Income Taxes .

Income from equity investees, net

Equity investees contributed a net loss of 261 million in 2004, compared to net income of 20 million in 2003. In addition to the Group's share of the net income or loss of equity investees for the year, this line also includes charges relating to companies accounted for by Aventis using the equity method, including inventory recorded at fair value as of August 20, 2004, the expensing of our share of acquired research, and amortization of goodwill and intangible assets of these companies.

Goodwill amortization

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Goodwill amortization amounted to 292 million in 2004, compared to 8 million in 2003. This increase reflects the amortization of goodwill arising from the acquisition of Aventis (283 million).

Minority interests

Minority interests made a positive contribution to net income of 7 million in 2004, compared to a negative contribution of 3 million in 2003. In 2004, net income from minority interests included a negative contribution of 4 million attributable to the minority shareholders of Hoechst and a positive contribution of 15 million attributable to other minority shareholders, corresponding to minority shareholders' share in the amortization of fair value remeasurements made to the acquired assets and liabilities of Aventis.

Consolidated net income/(loss)

As a result of the foregoing, we recorded a consolidated net loss of 3,610 million in 2004, compared to consolidated net income of 2,076 million in 2003.

Table of Contents*Year ended December 31, 2004 compared with year ended December 31, 2003***Unaudited Pro Forma Results of Operations**

We have prepared an unaudited pro forma statement of income for 2004 that presents our results of operations as if the acquisition had taken place on January 1, 2004. In accordance with French regulatory requirements, we have also prepared a comparative unaudited pro forma statement of income for 2003. The comparative unaudited pro forma statement of income presents our results of operations as if the acquisition had taken place on January 1, 2003. For a detailed description of the principles used to establish the pro forma financial statements, see Note D.1, section 5, to the consolidated financial statements.

Pro Forma Developed Sales

As discussed above, pro forma developed sales are an indicator of the worldwide market presence of sanofi-aventis products. Pro forma developed sales were 28,529 million in 2004, representing an increase of 12.3% over 25,402 million of pro forma developed sales in 2003 on a comparable basis.

The following table reconciles our pro forma comparable-basis developed sales and our pro forma comparable-basis net sales for the years ended December 31, 2003 and 2004 (pro forma comparable-basis net sales are reconciled to pro forma reported net sales under the heading Pro Forma Net Sales below):

<i>In millions of euros</i>	<u>2003</u>	<u>2004</u>
Pro forma comparable-basis net sales	23,110	25,418
Non-consolidated sales of Plavix®/Iscover®, net of sales of product to Bristol-Myers Squibb and related entities	1,733	2,414
Non-consolidated sales of Aprovel®/Avapro®/Karvea®, net of sales of product to Bristol-Myers Squibb and related entities	524	659
Non-consolidated sales of Stilnox®/Myslee®, net of sales of product to Fujisawa	35	38
Pro forma comparable-basis developed sales	25,402	28,529

The following table sets forth pro forma developed sales of Plavix® and Aprovel® in 2004 and 2003, broken down into three geographic markets:

<i>In millions of euros</i>	2003	2004	Change (%)
	Pro forma	Pro forma	Comparable
	comparable	<u>comparable</u>	<u>comparable</u>

Plavix®/Iscover®			
Europe			
United States	1,059	1,354	+27.9%
	1,658	2,289	+38.1%
Other countries	330	465	+40.9%
Sub-total	3,047	4,108	+34.8%
Aprovel®/Avapro®/Karvea®			
Europe			
United States	633	725	+14.5%
	366	455	+24.3%
Other countries	202	269	+33.2%
Sub-total	1,201	1,449	+20.6%
Total pro forma developed sales	25,402	28,529	+12.3%

Pro forma developed sales of Plavix® were 4,108 million in 2004, a 34.8% increase over 2003 on a comparable basis. In the United States, developed sales of Plavix® reached 2,289 million, an increase of 38.1% on a comparable basis. Plavix® sales in the United States, which are included in the developed sales totals but are not reflected in our consolidated net sales, resulted in part from an increase in overall U.S. demand for Plavix®, with overall prescription volume increasing by 23.5% from 2003 to 2004 (based on Prescriptions TRx IMS NPA 3 channels 2004). In Europe, Plavix® confirmed its leading status, with developed sales up 27.9% on a comparable basis at 1,354 million. In other countries, sales rose by 40.9% in 2004 compared to 2003 on a comparable basis.

Table of Contents

Pro forma developed sales of Aprovel® were 1,449 million in 2004, a 20.6% increase over 2003 on a comparable basis. In the United States, developed sales of Aprovel® reached 455 million, an increase of 24.3% over 2003 on a comparable basis. As with Plavi®, U.S. sales of Aprovel® are not included in our consolidated net sales, although they are included in developed sales. During 2004, overall U.S. demand for Aprovel® was up, with a 15.4% increase in overall prescription volume from 2003 to 2004 (based on Prescriptions TRx IMS NPA 3 channels 2004). In Europe and in the other countries, developed sales of Aprovel® increased by 14.5% and 33.2%, respectively, on a comparable basis over 2003.

Pro forma net sales

Our pro forma net sales were 25,418 million in 2004, an increase of 4.6% over pro forma net sales of 24,296 million in 2003, or an increase of 10.0% on a comparable basis. Our pro forma net sales were negatively impacted by 4.1 percentage points due to currency effects, more than two-thirds of which came from the decline in the US dollar against the euro (the remainder came mainly from Latin America and Japan). Changes in group structure, reflecting products divested by Aventis in 2003 and in the first half of 2004, had a net unfavorable impact of 1.3 percentage points on pro forma net sales growth.

The following table sets forth a reconciliation of our pro forma reported net sales for the year ended December 31, 2003 and our pro forma comparable-basis net sales for that year based on 2004 exchange rates and group structure:

<i>In millions of euros</i>	2003
<i>2003 pro forma reported-basis net sales</i>	<u>24,296</u>
Impact of changes in group structure	-289
Impact of exchange rates	-897
<i>2003 pro forma comparable-basis net sales</i>	<u><u>23,110</u></u>

The following tables reconcile our consolidated net sales to pro forma net sales, with a breakdown between our two main activities, pharmaceuticals and human vaccines, and by market (Europe, U.S. and other countries) for each of the years 2004 and 2003:

Reconciliation of 2004 consolidated net sales to pro forma net sales

<i>In millions of euros</i>	2004 net sales	Adjustments		2004 net sales
	consolidated	A	B	pro forma
Pharmaceuticals	14,360	9,969	-535	23,794
Human vaccines	683	941		1,624

Edgar Filing: SANOFI-AVENTIS - Form 20-F

	15,043	10,910	-535	25,418
	2004 net sales		Adjustments	
<i>In millions of euros</i>	consolidated	A	B	pro forma
Europe	7,351	4,218	-447	11,122
United States	4,658	4,124	-10	8,772
Other countries	3,034	2,568	-78	5,524
Total	15,043	10,910	-535	25,418

The adjustments between 2004 consolidated net sales and pro forma net sales relate to:

in column A, net sales generated by Aventis and its consolidated subsidiaries from January 1, 2004 to August 20, 2004; and

in column B, the pro forma divestment of Arixtra[®]/Fraxiparine[®] and Campto[®].

Table of Contents**Reconciliation of 2003 consolidated net sales to pro forma net sales**

<i>In millions of euros</i>	2003 net sales	Adjustments		2003 net sales
	consolidated	A	B	pro forma
Pharmaceuticals	8,048	15,240	-593	22,695
Behring		974	-974	0
Human vaccines		1,601		1,601
Total	8,048	17,815	-1,567	24,296

<i>In millions of euros</i>	2003 net sales	Adjustments		2003 net sales
	consolidated	A	B	pro forma
Europe	4,693	6,439	-477	10,655
United States	1,912	7,425	-1,002	8,336
Other countries	1,443	3,951	-88	5,305
Total	8,048	17,815	-1,567	24,296

The adjustments between 2003 consolidated net sales and pro forma net sales relate to:

in column A, non-consolidated net sales generated by Aventis in 2003, and

in column B, the pro forma divestment of Arixtra[®]/Fraxiparine[®], Campto[®] and Aventis Behring.

Pro forma net sales by product Pharmaceuticals

Pro forma net sales for our pharmaceuticals business were 23,794 million in 2004, an increase of 10.2% on a comparable basis (and 4.8% on a reported basis) over 2003. The main reason for this growth was the strong performance of our top 15 products, which represented 60.5% of pro forma net sales for our pharmaceuticals business in 2004, compared to 56.5% in 2003 (on a comparable basis).

The following table breaks down our pro forma net sales for the pharmaceuticals business by product:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>In millions of euros</i>	Indication	2003			Change (%)	
		2003 Pro forma reported	2003 Pro forma comparable	2004 Pro forma	Change (%)	
					Reported	Comparable
Lovenox®	Thrombosis	1,647	1,556	1,904	+15.6%	+22.4%
Plavix®	Atherothrombosis	1,325	1,314	1,694	+27.8%	+28.9%
Allegra®	Allergic rhinitis	1,740	1,614	1,502	-13.7%	-6.9%
Taxotere®	Breast cancer, lung cancer, prostate cancer	1,359	1,290	1,436	+5.7%	+11.3%
Stilnox®	Insomnia	1,345	1,234	1,423	+5.8%	+15.3%
Eloxatine®	Colorectal cancer	824	778	1,220	+48.1%	+56.8%
Delix®/Tritace®	Hypertension	1,182	1,176	972	-17.8%	-17.3%
Lantus®	Diabetes	498	469	843	+69.3%	+79.7%
Aprovel®	Hypertension	683	677	790	+15.7%	+16.7%
Copaxone®	Multiple sclerosis	620	583	742	+19.7%	+27.3%
Amaryl®	Diabetes	600	576	684	+14.0%	+18.8%
Actonel®	Osteoporosis, Paget's disease	194	191	305	+57.2%	+59.7%
Depakine®	Epilepsy	277	275	303	+9.4%	+10.2%
Nasacort®	Allergic rhinitis	278	259	287	+3.2%	+10.8%
Xatral®	Benign prostatic hyperplasia	222	220	281	+26.6%	+27.7%
Sub-total for the top 15 products		12,794	12,212	14,386	+12.4%	+17.8%
Other products		9,902	9,387	9,408	-5.0%	+0.2%
Total Pharmaceuticals		22,696	21,599	23,794	+4.8%	+10.2%

Table of Contents

Lovenox[®] was our largest product in terms of pro forma net sales in 2004. Pro forma net sales of the product were 1,904 million in 2004, up 22.4% on a comparable basis over 2003. Pro forma net sales of Lovenox[®] increased by 24.0% on a comparable basis in the United States to 1,138 million and by 20.2% in Europe to 580 million. Sales growth in the United States resulted from increased marketing and promotional efforts, started in 2003, and from patients switching from unfractionated heparins, which are estimated to still represent 71% of the U.S. market by volume across all indications (Solucient, October 2004), to low molecular weight heparins, such as Lovenox[®].

Pro forma net sales of Plavix[®] were 1,694 million in 2004, up 28.9% on a comparable basis over 2003. The continued strong level of growth in Plavix[®] since its launch in 1998 comes from both Europe and the other countries. The difference between reported growth and comparable growth is relatively small because U.S. sales are limited to sales of active ingredients to the alliance entities under the operational management of BMS.

Pro forma net sales of Allegra[®] decreased 6.9% on a comparable basis to 1,502 million in 2004. Pro forma net sales of Allegra[®] in the United States amounted to 1,197 million compared to 1,310 million on a comparable basis in 2003, reflecting price pressure from the introduction of OTC competitors in this market, largely offset by an increase in the product's market share (see Item 4. Information on the Company Principal Products and Competition).

In 2004, pro forma net sales of Taxotere[®] reached 1,436 million, up 11.3% on a comparable basis over 2003. The difference between the 11.3% increase in sales of Taxotere[®] on a comparable basis and the 5.7% on a reported basis is due to the weakness of the dollar, as we realize a significant portion of our Taxotere[®] sales in the United States. Pro forma sales increased by 31.0% in Europe to 502 million, with growth particularly strong in France. Pro forma sales of Taxotere[®] decreased by 1.1% in the United States on a comparable basis. Taxotere[®] has been at a disadvantage in the United States due to its reimbursement treatment, which, as expected, was changed as of January 1, 2005 and should lead to an improvement in sales of Taxotere[®] in 2005.

Pro forma net sales of Stilnox[®] reached 1,423 million, up 15.3% on a comparable basis over 2003. The difference between the 15.3% increase in sales of Stilnox on a comparable basis and the 5.8% on a reported basis is due to the weakness of the dollar, as we realize a majority of Stilnox[®] sales in the United States (marketed under the brand name Ambien[®]). Pro forma net sales of Stilnox[®] were 1,198 million in the United States in 2004, up 17.8% on a comparable basis. During 2004, overall U.S. demand for Stilnox[®] was up, with a 10.5% increase in overall prescription volume from 2003 to 2004 (based on Prescriptions TRx IMS NPA 3 channels 2004). Pro forma net sales of Stilnox[®] in Japan (marketed under the brand name Myslee[®]) increased 24.1% on a comparable basis to 60 million, as its market share continued to grow. See Item 4. Information on the Company Principal Products and Competition.

Pro forma net sales of Eloxatine[®] reached 1,220 million in 2004, up 56.8% on a comparable basis over 2003. Pro forma net sales increased by 73.5% in the United States on a comparable basis to 722 million and 35.7% in Europe to 410 million. The increase reflects primarily volume growth following the approval of Eloxatine[®] for new indications in the United States in 2004. In November 2004, the FDA approved Eloxatine[®] for the treatment of colon cancer following surgery. See Item 4. Information on the Company Principal Products.

Pro forma net sales of Tritace[®] amounted to 972 million in 2004, down 17.3% on a comparable basis over 2003, reflecting the impact of generics in Germany and the United Kingdom. However, the product registered double-digit growth in Canada and France where patents remain in force.

Pro forma net sales of Lantus[®] increased 79.7% on a comparable basis over 2003 to 843 million. This product, first launched in Germany in 2000, was launched in a number of other major markets in 2003. In 2004 in the United States, pro forma net sales of Lantus[®] increased 57.2% on

Edgar Filing: SANOFI-AVENTIS - Form 20-F

a comparable basis to 495 million, with Lantus[®] becoming the best-selling insulin brand in the United States. See Item 4. Information on the Company Principal Products and Competition. Pro forma net sales of Lantus[®] increased 111.4% on a comparable basis in Europe in 2004, reaching 295 million.

Pro forma net sales of Aprove[®] were 790 million in 2004, up 16.7% on a comparable basis. See Pro Forma Developed Sales above for more information.

Table of Contents

Pro forma net sales of Copaxone® were 742 million in 2004, up 27.3% on a comparable basis.

Pro forma net sales of Amaryl® amounted to 684 million in 2004, up 18.8% on a comparable basis. In 2004, pro forma net sales increased 32.0% in the United States, reaching 216 million, and 9.0% in Europe, reaching 239 million.

Pro forma net sales of Actonel® reached 305 million in 2004, up 59.7% on a comparable basis over 2003. In Japan, 2004 pro forma net sales of Actonel® were 46 million, up 56.5% on a comparable basis.

Pro forma net sales of Depakine® amounted to 303 million in 2004, up 10.2% on a comparable basis, with strong growth of 19.6% in the Other countries market.

Pro forma net sales of Nasacort® totaled 287 million in 2004, up 10.8% on a comparable basis.

Pro forma net sales of Xatral® totaled 281 million in 2004, up 27.7% on a comparable basis.

Pro forma net sales of other pharmaceutical products amounted to 9,408 million in 2004, stable on a comparable basis compared to 2003 (+0.2%). For a description of our other pharmaceutical products, see Item 4. Information on the Company Business Overview Other Pharmaceutical Products.

Pro forma net sales Human vaccines

Pro forma net sales of our human vaccines business were 1,624 million in 2004, representing an increase of 1.4% on a reported basis and 7.5% on a comparable basis. The difference between the increase in sales on a reported basis and on a comparable basis is due to the weakness of the dollar as we realize a significant portion of our sales of human vaccines in the United States.

The following table presents the sales of our human vaccines activity by vaccine type:

<i>In millions of euros</i>	2003		2004		Change (%)	
	2003	2003	2004	Change (%)	Change (%)	
	Pro forma Reported	Pro forma Comparable	Pro forma	Reported	Comparable	
Influenza vaccines	418	394	524	+25.4%	+33.0%	

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Pediatric combination vaccines	348	328	336	-3.4%	+2.4%
Polio vaccines	236	221	184	-22.0%	-16.9%
Adult booster vaccines	143	133	174	+21.7%	+30.1%
Travel vaccines	158	151	147	-7.0%	-2.6%
Meningitis vaccines	81	76	86	+6.2%	+13.1%
Other	216	208	173	-19.9%	-16.8%
	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>
Total Human Vaccines	1,601	1,511	1,624	+1.4%	+7.5%
	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>

The growth of our human vaccines business was mainly driven by growth in influenza vaccines, adult booster vaccines and meningitis vaccines. Influenza vaccines reported strong growth, especially in the northern hemisphere, due in part to increasingly broad government immunization recommendations in the United States. Pro forma net sales of pediatric combination vaccines decreased due to tough competition in the United States and Latin America. Pro forma net sales of polio vaccines saw a decline of 16.9% on a comparable basis, due mainly to increased use of combination vaccines. Adult booster vaccines were lifted by heavy demand for Adacel® in Canada and the Td vaccine in the United States. Travel vaccines were down slightly due to production problems during 2004. Demand for meningitis vaccines grew strongly among non-government purchasers in the United States, rising by 70% in 2004.

In Europe, our vaccines business is conducted through our joint venture with Merck & Co (Sanofi Pasteur MSD), the sales of which are accounted for using the equity method and therefore not included in pro forma net sales (we have an interest of 50% in Sanofi Pasteur MSD). Sanofi Pasteur MSD recorded sales of 651 million in 2004, an increase of 10.2% on a comparable basis against 591 million in 2003.

Table of Contents*Pro forma net sales by geographic area*

<i>In millions of euros</i>	2003	2003	2004	Change (%)	Change (%)
	Pro forma Reported	Pro forma Comparable	Pro forma	Reported	Comparable
Europe					
United States	10,655	10,500	11,122	+4.4%	+5.9%
	8,336	7,553	8,772	+5.2%	+16.1%
Other countries	5,305	5,057	5,524	+4.1%	+9.2%
Total	24,296	23,110	25,418	+4.6%	+10.0%

In Europe, our pro forma net sales amounted to 11,122 million, representing an increase of 4.4% on a reported basis and 5.9% on a comparable basis, with an increase of 4.3% in France and 5.3% in Germany. This growth was achieved despite difficult market conditions and the arrival of generic forms of Tritace®. Europe represented 43.8% of our total pro forma net sales in 2004, compared to 45.4% in 2003.

In the United States, our pro forma net sales reached 8,772 million, representing an increase of 5.2% on a reported basis and 16.1% on a comparable basis. The difference between reported and comparable sales is principally due to the weakness of the U.S. dollar compared to the euro. Growth in the United States was principally driven by the success of Lantus®, which had U.S. net sales of 495 million and 57.2% comparable-basis growth; Eloxatine®, which had U.S. net sales of 722 million euros and 73.5% comparable-basis growth; Loveno®, which had U.S. net sales of 1,138 million and 24.0% comparable-basis growth; and Ambie®, which had U.S. net sales of 1,198 million and 17.8% comparable-basis growth. The United States represented 34.5% of total pro forma net sales in 2004, compared to 32.7% in 2003.

In other countries, our pro forma net sales reached 5,524 million, representing an increase of 4.1% on a reported basis and 9.2% on a comparable basis. In Japan, pro forma net sales of our pharmaceuticals activity increased 4.7% in 2004 to 1,086 million, with sales growth of 56.5% for Actonel®, 23.7% for Amaryl® and 19.9% for Myslee®, all on a comparable basis. The other countries represented 21.7% of pro forma net sales in 2004, compared to 21.9% in 2003.

Pro forma gross profit

Our pro forma gross profit was 19,376 million in 2004, an increase of 4.7% compared to 2003, and represented 76.2% of our total pro forma net sales in both 2004 and 2003.

The overall stability in gross margin mainly reflects two opposing factors:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

a sharp increase in European government levies on the pharmaceuticals industry, representing a loss of margin of 0.4 of a percentage point; and

an increase in net royalty income from Plavix[®] and Aprovel[®], representing an increase of 0.3 percentage points in gross margin.

In 2004, we recognized royalty income of 650 million and made royalty payments of 63 million (compared to, respectively, 501 million and 51 million in 2003) under the worldwide alliance with Bristol-Myers Squibb on Plavix[®] and Aprovel[®].

Pro forma operating profit

Our pro forma operating profit was 8,163 million in 2004, representing a 12.5% increase compared to our pro forma operating profit in 2003 of 7,524 million.

Pro forma operating profit in 2004 represented 32.1% of pro forma net sales, compared to 29.9% in 2003, an increase of 2.2 percentage points. This improvement in pro forma operating profit and margin was driven by:

continued strong sales of our top 15 products, which were up 17.8% on a comparable basis at 14,386 million, representing 60.5% of pro forma net sales for our pharmaceuticals activity (compared to 56.5% in 2003), combined with stable sales of our other products taken as a whole;

Table of Contents

lower pro forma research and development expenses, which amounted to 3,961 million (15.6% of pro forma net sales) in 2004, representing a decrease of 2.6% compared to 2003 when milestone payments to biotechnology companies under collaboration agreements were at a particularly high level;

an increase of only 2.2% in pro forma selling and general expenses to 7,678 million in 2004, resulting from the efforts of both sanofi-aventis and Aventis to reduce recruitment following the announcement of the acquisition of Aventis in the first half of 2004; and

an increase in our net profit share from our alliances with BMS.

The following table breaks down our pro forma operating profit for 2004 and 2003 among its principal components:

<i>In millions of euros</i>	2003		2004		2003/2004
	Pro forma	As % of net sales	Pro forma	As % of net sales	Change (%)
Net sales	24,296	100.0%	25,418	100.0%	+4.6%
Cost of goods sold	(5,783)	(23.8%)	(6,042)	(23.8%)	+4.5%
Gross profit	18,513	76.2%	19,376	76.2%	+4.7%
Research and development expenses	(4,068)	(16.7%)	(3,961)	(15.6%)	-2.6%
Selling and general expenses	(7,515)	(30.9%)	(7,678)	(30.2%)	+2.2%
Other operating income/(expense), net	324	1.3%	426	1.7%	+31.5%
Pro forma operating income	7,254	29.9%	8,163	32.1%	+12.5%

Pro forma research and development expenses decreased to 3,961 million in 2004, representing 15.6% of our pro forma net sales and a decrease of 2.6% compared to 2003. The decrease is mainly due to a decrease in milestone payments, which were particularly significant in 2003 (117 million in 2003 compared to 38 million in 2004), and higher expenses on large-scale clinical trials in 2003 (especially on rimonabant and Lovenox®), which were completed during the course of 2004.

Pro forma selling and general expenses were 7,678 million in 2004, representing an increase of 2.2% over 2003. The successful efforts of both sanofi-aventis and Aventis in reducing recruitment following the announcement of the acquisition of Aventis in the first half of 2004 helped to limit the growth of these expenses.

Pro forma other operating income/(expense), net amounted to income of 426 million in 2004, an increase of 31.5% compared to 2003. As discussed above, this item reflects operating profits of our alliances (mainly, Bristol-Myers Squibb, Procter & Gamble Pharmaceuticals, Altana, Fujisawa, Sankyo and Teva) to which we are entitled or to which our partners are entitled. Overall, the increase in this item reflects strong growth for Plavix® and Aprovel® in Europe and the United States, and for Actonel® in the United States. In 2004, our profit share from sales of Plavix® and Aprovel® by our alliance entity under the operational management of BMS, mainly in North America, was 581 million, compared to 436 million in 2003. We paid to BMS profit shares of 257 million euros in 2004, compared to 173 million in 2003.

Pro forma amortization and impairment of intangibles

Pro forma charges for amortization and impairment of intangibles amounted to 3,950 million in 2004, after the elimination for pro forma purposes of 11 million of amortization relating to Arixtra® and Fraxiparine® and 94 million of amortization of Aventis intangible assets, and after recognition of a charge of 2,398 million for the amortization of the acquired intangible assets of Aventis. Overall, this represents a decrease of 5.3% relative to the 2003 pro forma figure of 4,171 million. The decrease in amortization was mainly due to the effect of exchange rates.

Pro forma net financial income/(expense)

Pro forma net financial income/(expense) amounted to a net expense of 599 million in 2004, compared to a net expense of 633 million in 2003. This change is mainly due to:

a decrease in interest expenses as a result of lower interest rates and an improvement in the overall cash position as a result of cash generated by operations;

Table of Contents

a charge of 76 million for impairment of investments in 2004, compared with 2 million in 2003.

Pro forma exceptional items

Pro forma exceptional items, net showed net expenses of 528 million in 2004, compared to 41 million in 2003. The significant increase in expenses in 2004 figure is mainly due to the following factors:

the inclusion of 557 million of restructuring charges in connection with the acquisition of Aventis; and

the inclusion of bid-defense costs of 156 million incurred by Aventis in connection with the offer by Sanofi-Synthélabo in 2004;

partially offset by:

the inclusion of Aventis restructuring costs pre-dating the acquisition in the amount of 140 million for 2004, compared to 218 million in 2003; and

charges and provisions relating to previously divested activities that amounted to 63 million in 2004, compared to 221 million in 2003. These divestments were unrelated to the acquisition of Aventis.

Net gains on disposals were largely stable at 420 million in 2004, compared to net gains of 428 million in 2003.

Pro forma income taxes

Pro forma income taxes amounted to 614 million in 2004, compared to 296 million in 2003. The 2003 and 2004 figures included major items with opposite effects: the income tax charge on ordinary activities (effective tax rate of 31.5% in 2004 versus 28.1% in 2003, when there were substantial reversals of provisions), and the deferred tax asset arising from the amortization of acquired intangible assets (rate of 37% in 2003 and 2004).

Pro forma income from equity investees, net

We recorded a net loss from equity investees of 88 million in 2004, compared to a net loss of 239 million in 2003. This change was due to trends in the results of the companies in which we hold equity interests:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

DyStar, the interest in which was sold during 2004, and which made a negative contribution of 32 million in 2004 and 105 million in 2003;

Rhodia, no longer equity-accounted in 2004, which made a negative contribution of 102 million in 2003; and

Wacker-Chemie, which recorded a profit in 2004 after heavy losses in 2003.

Pro forma goodwill amortization

Goodwill amortization decreased from 864 million in 2003 to 826 million in 2004, mainly as a result of exchange rate movements.

Pro forma minority interests

Pro forma income attributable to minority interests was 28 million in 2004, compared to 33 million in 2003.

Pro forma net income

As a result of the foregoing, our pro forma net income increased 74.6% from 977 million in 2003 to 1,706 million in 2004.

Table of Contents***Year Ended December 31, 2003 Compared to Year Ended December 31, 2002****Preliminary Note*

The discussion of our results of operations in 2002 and 2003 are based on our historical, consolidated financial statements for 2003, which do not reflect the results of operations of Aventis. As a result, the figures for 2003 below are not comparable to the pro forma 2003 figures or the historical or pro forma 2004 figures in the comparative discussion of 2003 and 2004 set forth above.

Developed Sales

Developed sales of our products were 10,560 million in 2003, representing a 10.2% increase over 2002. On a comparable basis, developed sales increased by 20.4% between 2002 and 2003. Plavix® and Aprovel® had combined developed sales of 4,480 million in 2003, a 22.6% increase over 2002, or 36.2% on a comparable basis. Sales of these two products accounted for 42.4% of total developed sales of our products, compared to 38.1% in 2002. Developed sales in 2002 were impacted by Bristol-Myers Squibb's program to reduce inventory levels of Plavix® and Aprovel® at wholesalers in the United States.

The following table reconciles our developed sales and our consolidated net sales for the year ended December 31, 2003:

<i>In millions of euros</i>	2003
Total Consolidated Net Sales	8,408
Plavix® non-consolidated sales less product sales to Bristol-Myers Squibb	1,900
Aprovel® non-consolidated sales less product sales to Bristol-Myers Squibb	572
Stilnox® non-consolidated sales less product sales to Fujisawa	36
Arixtra® non-consolidated sales	5
Total Developed Sales	10,560

The following table sets forth developed sales of Plavix® and Aprovel® in 2002 and 2003, broken down into our three geographic markets:

<i>In millions of euros</i>	Year Ended December 31,			% change	
	2002		2003	Reported	
	Reported	Comparable	Reported	Reported	Comparable
Plavix®/Iscover®					

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Europe	770	766	1,056	37.1%	37.9%
United States	1,565	1,318	1,817	16.1%	37.9%
Other Countries	252	221	352	39.7%	59.3%
	<u>2,587</u>	<u>2,305</u>	<u>3,225</u>	24.7%	39.9%
Aprovel®/Avapro®/Karvea®					
Europe	515	513	634	23.1%	23.6%
United States	373	313	407	9.1%	30.0%
Other Countries	180	158	214	18.9%	35.4%
	<u>1,068</u>	<u>984</u>	<u>1,255</u>	17.5%	27.5%
Total two products	<u>3,655</u>	<u>3,289</u>	<u>4,480</u>	22.6%	36.2%
Total developed sales	<u>9,585</u>	<u>8,768</u>	<u>10,560</u>	10.2%	20.4%

Developed sales of Plavix® were 3,225 million in 2003, a 24.7% increase over developed sales of 2,587 million in 2002. In the United States, developed sales of Plavix® reached 1,817 million, an increase of 16.1%, or 37.9% on a comparable basis, adjusting for the impact of the weak dollar. Plavix® sales in the United States, which are included in the developed sales totals but are not reflected in our consolidated net sales, saw an increase in overall U.S. demand for Plavix® in 2003, with overall prescription volume increasing by 26.8% from 2002 to 2003 (based on IMS retail, mail order and long-term care data). Additionally, we estimate that Plavix®

Table of Contents

inventory levels were at approximately 1 month at the end of December 2003 following the end of the BMS wholesaler inventory workdown program. In addition, prices increased for the product in the United States. In Europe and in the Other Countries, developed sales of Plavix[®] increased by 37.1% and 39.7%, respectively, in 2003 compared to 2002.

Developed sales of Aprovel[®] were 1,255 million in 2003, a 17.5% increase over developed sales of 1,068 million in 2002. In the United States, developed sales of Aprovel[®] reached 407 million, an increase of 9.1%, or 30.0% on a comparable basis, adjusting for the impact of the weak dollar. As with Plavix[®], U.S. sales of Aprovel[®] are not included in our consolidated net sales, although they are included in developed sales. During 2003, overall U.S. demand for Aprovel[®] was up, with a 14.9% increase in overall prescription volume from 2002 to 2003 (based on IMS retail, mail order and long-term care data). Favorable price movements in the United States also had a positive effect. Additionally, we estimate that Aprovel[®] inventory levels were at approximately 1 month at the end of December 2003 following the end of the BMS wholesaler inventory workdown program. In Europe and in the Other Countries, developed sales of Aprovel[®] increased by 23.1% and 18.9%, respectively, in 2003 compared to 2002.

Net Sales

We had total consolidated net sales of 8,048 million in 2003, an increase of 8.1% over net sales of 7,448 in 2002, or an increase of 15.6% on a comparable basis. Our net sales were negatively impacted by 7.2 percentage points due to currency effects, 4.0 percentage points of which was attributable to the weakness of the U.S. dollar compared to the euro, with the remainder due to the decrease in value of certain Latin American, Asian and other European currencies. Changes in the scope of consolidation had a negative impact of 0.3 percentage points, mostly attributable to the change in consolidation method to proportionate consolidation (51%) for our joint venture with Fujisawa in Taiwan in May 2002.

The following table sets forth a reconciliation between our reported sales for the year ended December 31, 2002 and our comparable sales for that year based on 2003 exchange rates and group structure:

<i>In millions of euros</i>	Year Ended December 31, 2002
<i>Reported</i>	7,448
Impact of change of group structure	(24)
Impact of exchange rate fluctuation	(460)
<i>Comparable</i>	6,964

Markets. We divide our sales into three markets: Europe, the United States and Other Countries. The following table breaks down our 2002 and 2003 consolidated net sales by market.

<i>In millions of euros</i>	Year Ended December 31,			% change	
	2002	2002	2003	Reported	Comparable
	Reported	Comparable	Reported	Reported	Comparable

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Europe	4,304	4,249	4,693	9.0%	10.4%
United States	1,689	1,439	1,912	13.2%	32.9%
Other Countries	1,455	1,276	1,443	(0.8%)	13.1%
<i>Total net sales</i>	7,448	6,964	8,048	8.1%	15.6%

In Europe, we had consolidated net sales of 4,693 million, representing an increase of 9.0% on a reported basis (or 10.4% on a comparable basis). This growth was achieved despite health-care cost containment measures enacted during 2003 in France and Germany, our two biggest European markets. Europe represented 58.3% of our total consolidated net sales in 2003 compared to 57.8% in 2002.

In the United States, our consolidated net sales reached 1,912 million, representing an increase of 13.2% on a reported basis, or 32.9% on a comparable basis. The difference between reported and comparable sales growth is principally due to the weakness of the U.S. dollar compared to the euro. Growth in the United States

Table of Contents

was principally driven by the success of Eloxatine[®], which had U.S. net sales of 460 million in 2003, more than quadruple 2002 U.S. net sales on a comparable basis and a 296.6% increase on a reported basis. In addition, U.S. sales of Stilnox[®] increased to 1,124 million in 2003, representing a decrease of 7.0% compared to 2002 on a reported basis (or growth of 10.6% on a comparable basis). The increase in U.S. sales of Stilnox[®] on a comparable basis was achieved despite a significant reduction in inventory levels compared to the end of 2002. The United States represented 23.8% of our total consolidated net sales in 2003 compared to 22.7% in 2002.

In the other countries, our consolidated net sales reached 1,443 million, representing a slight decrease of 0.8% on a reported basis, but an increase of 13.1% on a comparable basis. The principal reasons for the difference between reported and comparable growth are the weakness of certain Latin American and Asian currencies compared to the euro, as well as the change from full consolidation to proportionate consolidation (51% of our joint venture with Fujisawa in Taiwan). The other countries represented 17.9% of our total consolidated net sales in 2003 compared to 19.5% in 2002.

Products. Our ten biggest-selling products in 2003 had 5,420 million in total consolidated net sales for the year, representing an increase of 18.5% over 2002. Sales of our top ten products represented approximately 67.3% of our total consolidated net sales in 2003, compared to 61.4% in 2002.

The main reason for this growth was the strong performance of our four leading products, Plavix[®], Aprovel[®], Stilnox[®] and Eloxatine[®], which together had total net sales of 4,177 million, an increase of 24.2% over 2002 on a reported basis, or 34.9% on a comparable basis. Sales of our four leading products represented 51.9% of our total consolidated net sales compared to 45.1% in 2002.

The following table breaks down our consolidated net sales by product.

<i>In millions of euros</i>		Year ended December 31,			% change	
		2002 Reported	2002 Comparable	2003 Reported	Reported	Comparable
Product	Therapeutic Area					
Stilnox [®]	Central Nervous System	1,424	1,218	1,345	(5.5%)	10.4%
Plavix [®]	Cardiovascular/Thrombosis	987	964	1,325	34.2%	37.4%
Eloxatine [®]	Oncology	389	365	824	111.8%	125.8%
Aprovel [®]	Cardiovascular/Thrombosis	562	549	683	21.5%	24.4%
Fraxiparine [®] (1)	Cardiovascular/Thrombosis	324	314	319	(1.5%)	1.6%
Depakine [®]	Central Nervous System	267	258	277	3.7%	7.4%
Xatral [®]	Internal Medicine	182	178	222	22.0%	24.7%
Cordarone [®]	Cardiovascular/Thrombosis	162	154	146	(9.9%)	(5.2%)
Solian [®]	Central Nervous System	135	133	148	9.6%	11.3%
Tildiem [®]	Cardiovascular/Thrombosis	141	138	131	(7.1%)	(5.1%)
<i>Total of top 10 Products</i>		4,572	4,271	5,420	18.5%	26.9%
Others		2,876	2,693	2,628	(8.6%)	(2.4%)
<i>Total consolidated net sales</i>		7,448	6,964	8,048	8.1%	15.6%

(1) We sold our rights to this product in 2004.

Stilnox[®] was our largest product in terms of consolidated net sales. The difference between the 10.4% increase in sales of Stilnox[®] on a comparable basis and the 5.5% decline on a reported basis is due to the weakness of the dollar, as we realize a majority of Stilnox[®] sales in the United States (marketed under the brand name Ambien[®]). The growth in Stilnox[®] sales on a comparable basis included a reduction in inventory levels in the United States equivalent to an estimated 0.8 of a month's sales. Consolidated net sales of Stilnox[®] in Japan (where it is marketed under the brand name Myslee[®]) reached \$49 million, an increase of 16.7% on a reported basis and 28.9% on a comparable basis, making it the market leader in its therapeutic class in the Japanese market just three years after its launch (IMS data 2003).

Table of Contents

Consolidated net sales of Plavix® were 1,325 million in 2003, an increase of 34.2% over 2002. The strong level of growth in Plavix® came from both Europe, where it was approved for health-care reimbursement in both Italy and Portugal in 2003, and the other countries. The difference between reported growth and comparable growth was relatively small, as consolidated U.S. sales were limited to sales of active ingredients to the alliance entities under the operational management of BMS.

Consolidated net sales of Aprovel® were 683 million in 2003, an increase of 21.5% over 2002. Much of the growth was realized in Europe where Aprovel®, in terms of sales, became the no. 2 product in its class, angiotensin II receptor antagonists, in Europe and no. 1 in France, Belgium, Greece and Switzerland (according to IMS data 2003).

Consolidated net sales of Eloxatine® were 824 million in 2003, an increase of 111.8% over 2002. This resulted principally from strong growth in the U.S. market since its launch on August 30, 2002, with U.S. sales of 460 million in 2003. Outside the United States, Eloxatin® grew by 37.4% in Europe and 14.5% in the other countries.

Consolidated net sales of Xatral® increased by 22.0%, as sales of the product were boosted by the continued success of the once-a-day formulation that was gradually launched in various countries in Europe in 2002.

Among our other top 10 products, we recorded strong growth in sales of Solian®, while sales of Tildiem® and Cordarone® declined due to generic competition. Sales of Fraxiparine® (which was divested in 2004 in connection with the Aventis acquisition) were relatively flat.

Consolidated net sales of other products in our product portfolio decreased by 8.6% to 2,628 million in 2003, although they remained essentially stable on a comparable basis, declining by only 2.4%. The main reason for the difference between reported and comparable sales was due to currency effects. Excluding sales of Corotrope®, which declined by 71.7% in 2003 due to the introduction of generics in the U.S. market in May 2002 following expiration of its patent, and Ticlid®, which declined by 37.2% in connection with the gradual replacement of Ticlid® by Plavix®, the remaining products in our portfolio recorded slight growth of 2.2% in 2003 on a comparable basis (on a reported basis, they declined by 4.1% in 2003).

Gross Profit

Our gross profit was 6,620 million in 2003, an increase of 9.1% compared to 2002, and represented 82.3% of our total consolidated net sales in 2003, compared to 81.5% in 2002.

This improvement in our gross margin was mainly due to improvements in our productivity and overall product mix, which we estimate accounted for a 0.9 percentage point increase, as well as increased royalty payments on sales of Plavix® and Aprovel®, which we estimate accounted for a 0.3 percentage point increase.

These gains were partially offset by the significant increase in the government levies paid by pharmaceutical companies as part of healthcare reforms in Europe, notably in Germany, which we estimated accounted for a loss of 0.4 percentage points.

Operating Profit

Our operating profit was 3,075 million in 2003, representing a 17.6% increase compared to our operating profit in 2002 of 2,614 million. The weak U.S. dollar exchange rate against the euro had a negative impact on our operating profit, which would have increased by 34.4% over 2002 if exchange rates had remained constant. If net income arising from our hedging activities had been recognized at the operating level (rather than as financial income), operating profit would have increased by 19.4%.

Operating profit in 2003 represented 38.2% of consolidated net sales, while in 2002 operating profit was 35.1% of consolidated net sales. This improvement in our operating margins was driven principally by:

continued strong sales of our top 10 products, including rapid growth of Eloxatine[®] and strong growth of Plavix[®] and Aprovel[®]; and

an overall increase in the productivity of our sales force.

Table of Contents

The following table breaks down our operating profit for 2002 and 2003 among its principal components.

<i>In millions of euros</i>	Year ended December 31			
	2002		2003	
	Amount	% of Sales	Amount	% of Sales
<i>Net sales</i>	7,448	100.0%	8,048	100.0%
Cost of goods sold	(1,378)	(18.5%)	(1,428)	(17.7%)
<i>Gross profit</i>	6,070	81.5%	6,620	82.3%
Research and development expenses	(1,218)	(16.4%)	(1,316)	(16.4%)
Selling and general expenses	(2,428)	(32.6%)	(2,477)	(30.8%)
Other operating income/(expense), net	190	2.6%	248	3.1%
<i>Operating profit</i>	2,614	35.1%	3,075	38.2%

Research and development expenses increased to 1,316 million in 2003, representing 16.4% of our total consolidated net sales, and an 8.0% increase over 2002. Using 2002 exchange rates, the increase in our research and development expenses would have been 14.7%. The increase in spending was principally due to clinical trials that are underway both for new indications for products that are already on the market, such as Plavix[®], Aprovel[®], Eloxatine[®], Xatral[®] and Arixtra[®] (divested in 2004), as well as for new products in development, such as rimonabant, dronedarone, idraparinux sodium, xaliprodene and tirapazamine, and the sustained release formulation of Stilnox[®], zolpidem MR, among others.

Selling and general expenses were 2,477 million in 2003, representing 30.8% of our total consolidated net sales, and a 2.0% increase over 2002. Using 2002 exchange rates, our selling and general expenses would have increased by 9.2%. The increase was principally the result of our continued efforts to improve our commercial and marketing efforts in all of our geographic markets, which included:

the incurrence of significant costs relating to establishing the U.S. in connection with the launch of Xatral[®] in the United States in November 2003 (where it is marketed under the name UroXatral[®]); and

ongoing investments in our European marketing efforts.

Our other operating income/(expense), net was 248 million (or 3.1% of our net sales) in 2003, a 30.5% increase over 190 million in 2002. Using 2002 exchange rates, our other operating income would have increased by 71.1%. As discussed above, this item reflects operating profits of our alliances to which we are entitled or to which our partners are entitled, and is tied to an alliance with BMS. In 2003, our profit share from sales of Plavix[®] and Aprovel[®] by our alliance entity under the operational management of BMS, mainly in North America, was 436 million, compared to 348 million in 2002, with the increase reflecting in part the end of the BMS inventory workdown program. We paid to BMS profit shares from sales of these products under our operational management of 173 million in 2003, compared to 142 million in 2002.

Amortization and Impairment of Intangibles

Our amortization and impairment of intangibles remained stable at 129 million in 2003, the same amount as in 2002. The increase in amortization due to the repurchase of full rights to Lorex Pharmaceuticals joint venture from Pharmacia in April 2002 was offset by the weakness of the dollar compared to the euro.

Net Financial Income/(Expense)

Net financial income/(expense) increased from 85 million in 2002 to 155 million in 2003. This increase was principally due to a net foreign exchange gain of 103 million (compared to only 48 million in 2002) and by the reversal of a 2 million impairment provision against treasury shares held in connection with our stock option plans (compared to an increase of 46 million in the provision in 2002). These gains were only partially offset by a reduction in our invested cash position due to the share buyback program initiated in 2002, coupled with lower interest rates (which decreased on average by 1 percentage point).

Table of Contents

Exceptional Items

Exceptional income increased from 10 million in 2002 to 24 million in 2003. This increase was principally due to an additional payment received from the purchaser in connection with our divestiture of Sylachim in 2001.

Income Taxes

Income taxes increased by 312 million, from 746 million in 2002 to 1,058 million in 2003. Our effective tax rate was 33.9% in 2003 compared to 28.9% in 2002. The increase was principally attributable to an increase in consolidated net sales in the United States (due to strong sales of our leading products), as well as the establishment of provisions relating to tax audits in certain countries. The increase was also attributable to the fact that our 2002 rate had been particularly low due to the release of tax provisions of 53 million and the fact that we consolidated all of the operating profit of the Lorex joint venture, while we paid tax only on our profit share until our acquisition of Pharmacia's share in April 2002.

Minority Interests

Net income attributable to minority interests was 3 million in 2003 compared to 87 million in 2002. In 2002, net income attributable to minority interests represented primarily Pharmacia's share of the profits of the Lorex joint venture from January 1, 2002 through April 16, 2002.

Net Income

As a result of the foregoing, our net income increased 18.0% from 1,759 million in 2002 to 2,076 million in 2003. Using 2002 exchange rates, the increase would have been 31.6%. Net income per share in 2003 was 2.95 per share compared to 2.42 per share in 2002, or a 21.9% increase. The difference between the rate of growth in net income and in earnings per share was principally due to the share buyback program initiated in 2002, which decreased the number of outstanding shares.

Liquidity and Capital Resources

Our operations generate significant positive cash flow. We fund our investments primarily with operating cash flow and pay regular dividends on our shares. Following our acquisition of Aventis, we had net consolidated debt amounting to 14,160 million as of December 31, 2004.

Cash flow

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Given the acquisition of Aventis in 2004, and the inclusion of cash flows arising from the activities of Aventis and its subsidiaries from August 20, 2004, movements in consolidated cash flows between 2003 and 2004 are not representative of underlying trends in our activities.

Generally, factors that affect our earnings — for example, pricing, volume, costs and exchange rates — flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and human vaccines. Collections of royalty payments also contribute to cash from operations.

We believe that cash from operations is sufficient to meet our foreseen working capital requirements.

Net cash provided by operating activities came to 4,029 million, compared with 2,265 million in 2003.

Net cash used in investing activities totaled 14,142 million, against 350 million in 2003. The 2004 figure includes 14.3 billion for the cash payment to Aventis shareholders in connection with the acquisition of Aventis, net of cash acquired.

Table of Contents

Net cash provided by financing activities came to 9,222 million, compared with net cash used in financing activities of 1,598 million in 2003. The 2004 figure includes the 10.5 billion of external financing for the acquisition of Aventis, and the dividend payment to shareholders.

After taking account of the impact of exchange rate fluctuations, the net change in cash and cash equivalents during 2004 was a decrease of 914 million, compared with an increase of 300 million during 2003.

Consolidated balance sheet and debt

The balance sheet total was 76,755 million as of December 31, 2004, an increase of 67,006 million on the figure as of December 31, 2003 (9,749 million).

The main changes in the balance sheet were attributable to the financing of the Aventis acquisition and to the first-time consolidation of Aventis from August 20, 2004 (the assets and liabilities of Aventis were recognized at fair value as of the acquisition date).

Shareholders' equity increased from 6,323 million as of December 31, 2003 to 35,574 million as of December 31, 2004. This rise was due mainly to the capital increase of 1,357 million (new shares issued as consideration for the Aventis shares tendered into the offer, and then exchanged in connection with the merger of Aventis into sanofi-aventis), and the related increase of 36,192 million in additional paid-in capital and reserves.

As of December 31, 2004, the Group held 63.9 million of its own shares, representing 4.53% of the share capital and including 27.3 million shares acquired as a result of Aventis tendering its treasury shares into the offer. Sanofi-aventis did not repurchase any of its own shares in 2004.

The main balance sheet items with significant changes relative to December 31, 2003 were:

- long-term debt, which amounted to 8,638 million (an increase of 8,585 million relative to December 31, 2003), as a result of the debt used to finance the Aventis acquisition (see "Financing of Aventis acquisition" below);
- other long-term liabilities, which rose by 5,014 million to 5,768 million;
- short-term debt, which rose by 7,073 million, accompanied by a decrease of 888 million in short-term investments and cash and cash equivalents, in connection with the financing of the cash portion of the Aventis acquisition;
- net intangible assets, which increased by 52,054 million, principally as a result of the goodwill recognized on the Aventis acquisition (net goodwill rose by 23,351 million) and the inclusion at fair value of Aventis intangible assets (other intangible assets increased by 28,703 million);

Edgar Filing: SANOFI-AVENTIS - Form 20-F

- accounts receivable and accounts payable, which rose by 3,010 million and 2,108 million respectively, to 4,501 million and 2,765 million, as a result of the growth of the Group's business and the first-time consolidation of Aventis from August 20, 2004;
- inventories, which rose by 2,259 million following the inclusion of inventories of Aventis products at fair value;
- other current assets and liabilities, which rose by 1,579 million and 3,232 million respectively due to the first-time consolidation of Aventis from August 20, 2004.

As of December 31, 2004, consolidated net debt stood at 14,160 million compared to a net cash position of 2,397 million as of December 31, 2003. These figures do not include treasury shares held in connection with stock option plans, amounting to a net total of 624 million at end December 2004 (compared to 613 million at end December 2003).

Consolidated net debt is defined as long-term debt plus short-term debt, minus cash and cash equivalents and short-term investments (excluding treasury shares held in connection with stock option plans).

Table of Contents

Financing of the Aventis acquisition

On April 24, 2004, we signed a credit facility agreement for a maximum of 16 billion, to be used primarily to finance the cash portion of the offer for Aventis and to refinance some of the debt carried by Aventis and its subsidiaries.

On August 20, 2004, we financed the settlement of the cash portion of the offer (representing a total amount of 14.8 billion) as follows:

- Tranche A credit facility of 5 billion used in full;
- Tranche B credit facility of 5.5 billion used in full;
- commercial paper of 0.9 billion; and
- the balance paid from available cash.

On September 24, 2004, we financed the aggregate cash consideration of 410 million paid in settlement of the purchase of the Aventis shares tendered into the offers during the subsequent offering period ended September 6, 2004, as follows:

- commercial paper of 50 million; and
- the balance paid from available cash.

On September 30, 2004, we financed the aggregate cash dividend of 645 million in respect of the sanofi-aventis shares issued in exchange for the Aventis shares tendered into the offers (other than the sanofi-aventis shares issued in exchange for the Aventis treasury stock tendered in the offers), as follows:

- commercial paper of 430 million; and
- the balance paid from available cash.

The credit facility agreement contains customary contractual terms for financing of this type. In particular, it includes early repayment clauses triggered by non-compliance with the following financial ratios:

Consolidated net debt may not exceed two-and-a-half times consolidated EBITDA (as contractually defined, see below).

Edgar Filing: SANOFI-AVENTIS - Form 20-F

The sum total of the net debt of our subsidiaries, on a consolidated basis and excluding sums borrowed under the credit facility agreement, may not exceed our consolidated EBITDA.

Consolidated EBITDA is generally defined as operating profit after adding back (1) any amortization and depreciation charges, and additions to provisions, (2) any purchase-accounting charge in respect of acquired research and development in progress or a write-up of inventory to fair value that we were required to take as a result of the acquisition of Aventis, and (3) any restructuring charge of up to a maximum of 1 billion per year incurred in 2004 or 2005 that is incurred directly in connection with our acquisition of Aventis).

There credit facility agreement also contains customary restrictions on our ability, in general, to create any security interest in our assets, to sell, lease, transfer or dispose of our assets (unless, in general, the net proceeds are applied to prepaying borrowings under the credit facility), to make acquisitions or investments outside the ordinary course of business in an aggregate amount in excess of 10 billion, to enter into a merger or amalgamation (other than with a subsidiary) or to issue any bonds (unless, in general, the net proceeds are applied to prepaying borrowings under the credit facility).

Refinancing Carried out in 2005

For 2005, we have aimed to refinance substantially all of our Aventis acquisition financing in order to reduce our cost of debt, eliminate the restrictive financial covenants described above at Financing of the Aventis acquisition and enhance the liquidity profile of the company.

Table of Contents

On January 24, 2005, we repaid in full at its maturity date the 5 billion drawn on Tranche A of the acquisition financing by borrowing 5 billion through our French and American commercial paper programs. To provide back-up liquidity to the French and American commercial paper programs, we also entered into 364-day credit agreements making available 6.2 billion in credit. These back-up credit facilities consist of:

A 5 billion 364-day syndicated revolving credit facility including four extension options of the revolving termination date and a one year term-out option;

Three 364-day bilateral revolving credit facilities, for a total commitment of \$1.6 billion.

On March 31, 2005, we entered into a new 10 billion refinancing, consisting of four separate three-year bilateral facilities for a total of 2 billion and an 8 billion multi-currency syndicated revolving credit facility consisting of two tranches:

5.5 billion five-year tranche with the possibility of extending the maturity up to seven years; and

2.5 billion seven-year tranche.

On April 8, 2005, we drew down 5.5 billion from the new 10 billion refinancing to repay in full the 5.5 billion loan drawn against Tranche B of the acquisition financing and rely upon the undrawn portion of the 10 billion refinancing to early terminate 4.5 billion of the 5.5 billion revolving credit line available under Tranche C of the acquisition financing.

Liquidity

We expect that our existing cash resources will be sufficient to finance our existing ongoing activities and investments. In 2004, our overall liquidity position has changed significantly as a consequence of the success of our acquisition of Aventis, due to the fact that we have incurred substantial debt under our credit facility. See Financing of the Aventis acquisition and Refinancing carried out in 2005, above. We do not anticipate any significant increase in our capital expenditures in 2005 compared with recent years (excluding the Aventis acquisition in 2004), and we have no current plans that would result in a significant increase for the next several years.

Off-Balance Sheet Arrangements

Contractual Obligations and Other Commercial Commitments

We have various contractual obligations and other commercial commitments arising from our operations. These obligations and commitments are more fully described at Item 4. Information on the Company in this annual report.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

The following table lists the aggregate maturities of our contractual obligations given as of December 31, 2004.

Contractual obligations given	Payments due by Period				
	Total	Under 1 Year	1-3 Years	3-5 Years	Over 5 Years
<i>In millions of euros</i>					
Long-term debt, excluding capital lease obligations	8,840	239	6,951	18	1,632
Capital lease obligations (including interest)	70	10	14	12	34
Operating leases	1,087	227	322	220	318
Irrevocable purchase obligations	1,278	770	278	67	163
Other long-term obligations	781	612	75	75	19
Total	12,056	1,858	7,640	392	2,166

Table of Contents

The following table lists the aggregate maturities of our other commercial commitments as of December 31, 2004.

Other commercial commitments	Commitments by Period				
	Total	Under 1 Year	1-3 Years	3-5 Years	Over 5 Years
<i>In millions of euros</i>					
Credit facilities (a)	(11,802)	(3,749)	(1,592)	(5,950)	(511)
Letters of credit					
Guarantees:					
given	283	92	60	109	22
received	(97)	(73)	(2)		(22)
Repurchase commitments					
Other commercial commitments					
Total	(11,616)	(3,730)	(1,534)	(5,841)	(511)

- (a) The financing arrangements for our offers for Aventis included a credit facility of a maximum of 16 billion split into three tranches (see note D.14 Long-term debt portion due after more than one year in our consolidated financial statements). The amounts borrowed under Tranche C were intended to be used principally to finance payment of the costs associated with the acquisition of Aventis and to refinance some of the debt carried by Aventis and its subsidiaries. To the extent that these amounts were not used to finance the cash portion of the offers for Aventis, they may be borrowed in euros, US dollars or yen.

As of December 31, 2004, we had given a total of 23,672 million in commercial commitments, 5,588 million of which is payable within one year, 9,174 million of which is payable between one to three years, 6,233 million of which is payable between three to five years and 2,677 million of which is payable in more than five years from such date. For additional information regarding our commercial commitments, see Note D.19 to our consolidated financial statements included under Item 18.

In addition, we may have payments due to our current or former research and development partners under collaborative agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaborative partner a fee and receive intellectual property rights to the product in exchange. We also are generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

The main collaboration agreements into which we have entered are as follows:

A collaboration agreement with Cephalon on the development of angiogenesis inhibitors, under which our payments for the first product could reach \$32 million.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

A strategic collaboration agreement signed in 2001, under which IDM granted us 20 development options on current and future research and development programs. For each option that leads to a commercially marketed product, we may be required to pay IDM a total of between 17 million and 32 million, depending on the potential of the market, plus reimbursement of the development costs. Contractually, we may suspend the development program for each option exercised at any time and without penalty. As of December 31, 2004, we had exercised only one option, relating to a program for the treatment of melanoma. Because of the uncertain nature of development work, it is impossible to predict whether we will exercise further options for products or whether the expected milestones will be achieved, or for us to predict the number of compounds that will reach the relevant milestones. For this reason, it is impossible for us to estimate the maximum aggregate amount that we will actually pay in the future. We believe it is highly unlikely that we will exercise all options for all products or that all milestones will be achieved.

Table of Contents

Regeneron: In January, 2005, we reaffirmed our commitment to develop, in collaboration with Regeneron Pharmaceuticals Inc., the Vascular Endothelial Growth Factor (VEGF) Trap program in the field of oncology. The two companies will evaluate the VEGF trap in a variety of cancer types. We made a clinical development milestone payment of 20 million (\$25 million) to Regeneron in connection with this during 2004. If the program leads to the development of a commercially-marketed product, we could be required to pay Regeneron a further amount of 32 million (\$40 million).

A collaboration agreement with Zealand Pharma signed in June 2003, under which we obtained rights relating to the development and worldwide marketing of ZP10, an agent used in the treatment of type 2 diabetes. Under the agreement, we are responsible for the development of this compound and could, if marketing approvals are obtained, be required to pay Zealand Pharma a total of 60 million over the next 5 years.

Contingent payments that we may be required to make during the next 5 years under other collaboration agreements with Ajinomoto, Immunogen and Coley amount to approximately 26 million.

Transition to IFRS

Like all European listed companies, we are required to apply International Financial Reporting Standards (IFRS) in the preparation of our consolidated financial statements for financial years starting on or after January 1, 2005.

The reconciliation note to IFRS as of December 31, 2004 is presented at Exhibit 99.2 to this annual report.

US GAAP Reconciliation and Presentation Differences

We prepare our consolidated financial statements in accordance with French GAAP, which differ in certain significant respects from U.S. GAAP. As a result, our net income and shareholders' equity is different under U.S. GAAP and under French GAAP. For a detailed discussion of the differences between French GAAP and U.S. GAAP as they relate to our consolidated net income and shareholders' equity, see Note F to our audited consolidated financial statements included under Item 18.

Net Income

The following table sets forth our net income under French GAAP and U.S. GAAP for the periods indicated.

	Year Ended December 31,		
	2002	2003	2004
	<i>(in millions of)</i>		
<i>French GAAP net income</i>	1,759	2,076	(3,610)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Purchase accounting adjustments	(311)	(269)	(100)
Provisions and other liabilities			28
Stock-based compensation	(8)	(50)	(111)
Revenue recognition U.S. BMS alliance	117	33	
Other	31	(16)	(21)
Deferred income tax effects on above adjustments	54	94	93
Deferred income tax on equity investees	(2)	(3)	56
	<u> </u>	<u> </u>	<u> </u>
<i>U.S. GAAP net income</i>	1,640	1,865	(3,665)
	<u> </u>	<u> </u>	<u> </u>

Purchase accounting. The purchase accounting adjustments, amounting to a charge of 311 million in 2002, 269 million in 2003, 100 million in 2004, relate mainly to the business combination of Sanofi and Synthelabo in 1999 and the business combination of Sanofi-Synthelabo and Aventis in 2004.

- Regarding the business combination of Sanofi and Synthelabo, the transaction was accounted for under French GAAP as a merger. As a result, no goodwill was recorded in connection with the merger, and existing assets and liabilities of Sanofi and Synthelabo were revalued to adjust them to

Table of Contents

their value to our company. Under U.S. GAAP, the business combination is accounted for as a purchase, with Sanofi deemed the acquirer of Synthelabo. The transaction resulted in the recognition of significant goodwill and intangible assets. Beginning in 2002, we no longer amortize goodwill, but instead test goodwill annually for impairment in accordance with Statement of Financial Accounting Standards N°. 142. As no goodwill impairment has been identified in 2002, 2003 and 2004, this item reflects primarily the depreciation and impairment of intangible assets recognized under U.S GAAP.

- The business combination of Sanofi-Synthelabo and Aventis in 2004 was accounted for under French GAAP as a purchase by Sanofi-Synthelabo of Aventis. The goodwill resulting from this business combination, after allocation of the purchase price to the assets and liabilities acquired as amortized under French GAAP over a period of 30 years. The U.S.GAAP adjustment related to this transaction amounted to 289 million in 2004 and reflects the reversal of the goodwill amortization recognized under French GAAP.
- Under French GAAP, no goodwill or intangible assets associated with certain other acquisitions made by the Sanofi Group before June 30, 1999 are reflected in the sanofi-aventis consolidated financial statements. Under US GAAP, certain intangible assets were initially valued and recorded, and were amortized over their estimated useful lives. This adjustment amounted to 46 million in 2002, 20 million in 2003 and 31 million in 2004.

Provisions and other liabilities. The adjustment corresponds to the reversal of certain provisions for restructuring recorded under French GAAP in 2004 and that do not meet the FAS 146 Accounting for Costs Associated with Exit or Disposal Activities" criteria for recognition.

Stock-based compensation. Under French GAAP, we do not recognize compensation expense related to stock-based compensation. Shares issued upon the exercise of stock options are reflected as an increase in share capital upon exercise of the stock option. Under U.S.GAAP, prior to 2003, if the exercise price of the stock options was less than the market price of the underlying shares on the grant date, we recognized compensation expense over the related vesting period. Beginning in 2003, we adopted the fair value recognition provisions of Statement of Accounting Standards N° 123, using the modified prospective method under Statement of Accounting Standards N° 148, and we now recognize compensation expense over the vesting period based on the fair value of the option on the grant date. This resulted in an additional charge under U.S.GAAP of 50 million in 2003 and of 111 million in 2004.

Deferred tax on equity investees. Under French GAAP, a deferred tax liability is recorded for a taxable distribution when such distribution is considered probable. Under US GAAP, a deferred tax liability is recorded for the difference between the value considered in the financial reporting and the tax basis of equity-method investment in certain circumstances.

Presentation Differences

In addition to the foregoing, there are differences in presentation between our French GAAP and U.S. GAAP financial statements, which have no impact on our net income or shareholders' equity, but instead impact classification and presentation. The principal presentation differences are the following:

Under French GAAP, the Alliance entities majority-owned by BMS are presented in a manner similar to the equity method with our share of the operating profit recorded in other operating income/(expense) in our statements of income. Alliance entities that we majority-own are consolidated, with BMS' share of the operating profit recorded as a charge in other operating income/(expense) in our statements of income. Under US GAAP, the alliance entities majority-owned by BMS are presented as equity method investees with our share of the operating profits of the Alliance recorded as income from equity method investees in our statement of income. Alliance entities that we majority-own are fully consolidated in the condensed US GAAP financial statements with BMS' share of the operating profit presented in minority interests in our statement of income.

Table of Contents

Exceptional items. Certain amounts presented under French GAAP, as exceptional income and expense, such as gains or losses on disposals of tangible and intangible fixed assets, costs associated with strategic restructuring programs and significant costs or provisions related to litigation in our statement of income are treated as operating income or expenses under U.S.GAAP. As a result, these items impact our operating income under U.S.GAAP, while they do not impact our operating income under French GAAP.

Under French GAAP, we record license income and specific government levies related to the pharmaceuticals sector paid in certain countries in cost of goods sold. Under US GAAP, license income is reflected as Revenues, and specific government levies related to the pharmaceuticals sector are reflected either as a deduction of sales or in selling and general expenses depending on the substance of such levies.

Shareholders' Equity

The following table sets forth our shareholders' equity under French GAAP and U.S. GAAP as of the dates indicated.

	As of December 31,		
	2002	2003	2004
	<i>(in millions of €)</i>		
<i>French GAAP shareholders' equity</i>	6,035	6,323	35,591
Purchase accounting adjustments	8,576	8,267	7,930
Provisions and other liabilities			28
Stock-based compensation			
Revenue recognition - U.S. BMS alliance	(35)		
Other	(695)	(635)	(541)
Deferred income tax effects on above adjustments	(1,264)	(1,198)	(1,151)
Deferred income tax on equity investees	(18)	(21)	(225)
<i>U.S. GAAP shareholders' equity</i>	12,599	12,736	41,632

The principal factor affecting the determination of our shareholders' equity under U.S.GAAP was the purchase accounting treatment under the merger with Synthelabo, which resulted in shareholders' equity under U.S.GAAP being 8,465 million more in 2002, 8,170 million more in 2003 and 7,812 million more in 2004. These differences were partially offset by the impact of the deferred income taxes. The accounting treatment of the Aventis acquisition which was treated under French GAAP and U.S.GAAP as a purchase, had a limited impact on our shareholders' equity under U.S.GAAP. This amounted to 52 million as of December 31, 2004, due to the cumulative effect of the difference between the goodwill determined under French and U.S.GAAP and the French GAAP accumulated amortization of 289 million. The differences relate to the measurement of purchase price and the allocation of the purchase price resulting in a goodwill lower under U.S.GAAP by 236 million. The difference in the purchase price measurement is due to a difference in the date of measurement and the recognition in the purchase price of a portion of the existing Aventis stock option plans at fair value.

Recent Accounting Pronouncements

The U.S. Financial Accounting Standards Board (FASB), issued the following recent accounting pronouncements in 2004, which are applicable to our company.

SFAS No. 151, *Inventory Costs*, requires fixed production overhead absorption in inventory to be based on normal production capacity, with abnormal costs expensed. We do not expect adoption to have any effect on our consolidated financial statements.

SFAS 153 replaces the exception from fair value measurement in APB Opinion No. 29 with a general exception from fair value measurement for exchanges of nonmonetary assets that do not have commercial substance. We do not expect that the adoption of SFAS 153 will have a material effect on our financial statements.

Table of Contents

EITF 03-01, *The Meaning of Other Than Temporary Impairment and its Application to Certain Investments* was issued in March 2004, and contains additional guidance for determining when an investment is impaired. The effective date for applying this guidance is currently suspended pending the issue of a further FASB Staff Position statement. Adoption of the additional guidance is not expected to have a material effect on our consolidated financial statements.

EITF 04-10, *Determining Whether to Aggregate Operating Segments That Do Not Meet the Quantitative Thresholds*, was ratified in October 2004, and contains additional guidance on when an operating segment should be reported as a separate segment in the segmental analysis in the notes to the financial statements. We have adopted EITF 04-10 in these consolidated financial statements. Adoption of EITF 04-10 had no effect on the consolidated financial statements.

Critical accounting and reporting policies

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the estimates, judgments and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have identified as fundamental to a full understanding of our results of operations and financial condition are the following:

Treatment of Alliances. Our policies with respect to alliances are discussed above under *Overview Financial Presentation of Alliances* and *Overview Sources of Revenues and Expenses*. While our treatment of alliances does not require us to make significant estimates, an understanding of our income statement requires an understanding of the presentation of the results of our alliances, including the presentation of royalties paid and received in our cost of sales, and the presentation of our share of profits from our alliances under *Other operating income / (expense), net*.

Impairment Testing. We test our intangible assets periodically for impairment. The most significant intangible assets that we test for impairment are those resulting from the U.S. GAAP treatment of business combinations, as discussed above under *U.S. GAAP Reconciliation and Presentation Differences Net Income*. We test for impairment on the basis of the same objective criteria that are used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial valuation) or the recorded value of the asset (for ongoing tests). The determination of the underlying assumptions related to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Any changes in key assumptions about our business and prospects, or changes in market conditions, could result in an impairment charge.

Pension and Retirement Benefits. We recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the potential rights vested in employees and retirees as of the balance sheet date, net of the valuation of funds to meet these obligations. We prepare this estimate on an annual basis taking into account actuarial assumptions, including life expectancy, staff turnover, salary growth, long-term return on plan assets, retirement and discounting of amounts payable. Depending on the assumptions and estimates used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings.

Deferred Taxes. We account for deferred taxes using the liability method, whereby deferred income taxes are recognized on tax loss carry-forwards, and the difference between the tax and carrying amount of assets and liabilities. We calculate our deferred tax assets and liabilities using enacted tax rates applicable for the years during which we estimate that the temporary differences are expected to reverse. We record a provision when it is more likely than not that the realization of the deferred tax assets will not occur.

Table of Contents

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Board of Directors

The company is managed by a Board of Directors composed of 17 members, 10 of whom are independent.

Members of our Board of Directors are appointed for a maximum term of 4 years. No more than one-third of the serving members of our Board of Directors may be aged more than 70.

The age limit for holding office as Chairman or Chief Executive Officer is 68 years.

Subject to the authority expressly reserved by law to the shareholders, and within the scope of the corporate objects, the Board of Directors deals with and takes decisions upon issues relating to the proper management of the company and other matters concerning the Board.

Under our bylaws (*statuts*), each member of the Board of Directors must be the direct legal owner of at least one of our shares throughout his or her term of office.

At December 31, 2004, non-executive members of the Board of Directors collectively held a total of 273,293 sanofi-aventis shares.

Table of Contents**Composition of the Board of Directors at December 31, 2004**

Jean-François Dehecq	Age	65
Chairman and Chief Executive Officer	First elected	<i>May 1999</i>
	Term expires	<i>2008</i>
	Principal occupation	Chairman and Chief Executive Officer of sanofi-aventis
	Other directorships and appointments	. Director of Air France . Chairman and Director of Sanofi-Synthélabo Daiichi Pharmaceuticals Co Ltd (Japan) . Director of Sanofi-Synthélabo Inc. (United States) and Fujisawa Sanofi-Synthélabo (Japan)
Jürgen Dormann	Age	65
Vice-Chairman Independent Director	First elected	<i>August 2004</i>
	Term expires	<i>2008</i>
	Principal occupation	Chairman of ABB Ltd (Switzerland)
	Other directorships and appointments	. Director of Adecco (Switzerland)
René Barbier de la Serre	Age	64
Independent Director	First elected	<i>May 1999</i>
	Term expires	<i>2008</i>
	Principal occupation	Member of the Supervisory Board of La Compagnie Financière Edmond Rothschild Banque
	Other directorships and appointments	. Director of Calyon and Schneider Electric . Member of the Supervisory Boards, La Compagnie Financière Saint-Honoré, Pinault-Printemps-Redoute and Euronext NV (Netherlands) . Delegated Director of Harwanne Compagnie de Participations Industrielles et Financières SA (Switzerland)
Jean-Marc Bruel	Age	69

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Independent Director

First elected

August 2004

Term expires

2008

Principal occupation

Chairman of La Fondation
Villette-Entreprises and Firmenich

Other directorships and appointments

. Director of Rhodia, Institut Curie and
Ecole Centrale

Table of Contents

Robert Castaigne	Age	58
Director	First elected	<i>February 2000</i>
	Term expires	<i>2008</i>
	Principal occupation	Chief Financial Officer of Total SA
	Other directorships and appointments	. Chairman and Chief Executive Officer of Total Chimie and Total Nucléaire . Director of Arkema, Elf Aquitaine, Hutchinson, Total Gestion Filiales, Omnium Insurance & Reinsurance Company Ltd (Bermuda), Petrofina (Belgium), Total Holdings UK and Total Gabon
Thierry Desmarest	Age	59
Director	First elected	<i>February 2000</i>
	Term expires	<i>2008</i>
	Principal occupation	Chairman and Chief Executive Officer of Total SA and Elf Aquitaine
	Other directorships and appointments	. Member of the Supervisory Boards of Areva and L Air Liquide
Lord Douro	Age	59
Independent Director	First elected	<i>May 2002</i>
	Term expires	<i>2006</i>
	Principal occupation	Chairman of Richemont Holdings UK
	Other directorships and appointments	. Chairman of Framlington group (United Kingdom) . Director of La Compagnie Financière Richemont AG (Switzerland) and GAM Worldwide (United Kingdom)
Jean-René Fourtou	Age	65
Independent Director	First elected	<i>August 2004</i>
	Term expires	<i>2008</i>
	Principal occupation	Chairman and Chief Executive Officer of Vivendi Universal
	Other directorships and appointments	. Chairman of the Supervisory Board of Canal +

Edgar Filing: SANOFI-AVENTIS - Form 20-F

		. Vice-Chairman of the Supervisory Board of Axa
Serge Kampf	Age	. Director of Cap Gemini 70
Independent Director	First elected	<i>August 2004</i>
	Term expires	2008
	Principal occupation	Chairman of Cap Gemini SA
	Other directorships and appointments	. Chairman of Cap Gemini Service and Cap Gemini Suisse . Director of Sogeti-Transiciel and Cap Gemini North America Inc.

Table of Contents

Igor Landau	Age	60
Director	First elected	<i>August 2004</i>
	Term expires	<i>2008</i>
	Principal occupation	Director of Thomson, Essilor, CCF and INSEAD
	Other directorships and appointments	. Member of the Supervisory Boards of Dresdner Bank, Allianz and Adidas-Salomon
Hubert Markl	Age	66
Independent Director	First elected	<i>August 2004</i>
	Term expires	<i>2008</i>
	Principal occupation	Professor of biology, retired
	Other directorships and appointments	. Member of the Supervisory Boards of BMW AG, Münchener Rückversicherungs-Gesellschaft and Royal Dutch Shell
Christian Mulliez	Age	44
Director	First elected	<i>June 2004</i>
	Term expires	<i>2008</i>
	Principal occupation	Vice President, General Management, Administration and Finance of L'Oréal
	Other directorships and appointments	. Chairman and Director of Regefi . Director of DG 17 Invest and L'Oréal USA Inc.
Lindsay Owen-Jones	Age	59
Director	First elected	<i>May 1999</i>
	Term expires	<i>2008</i>
	Principal occupation	Chairman and Chief Executive Officer of L'Oréal
	Other directorships and appointments	. Director of BNP Paribas . Vice Chairman and member of the Supervisory Board of Air Liquide
Klaus Pohle	Age	67

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Independent Director

First elected

August 2004

Term expires

2008

Principal occupation

Chairman of the German Accounting Standards Board (GASB)

Other directorships and appointments

. Director of Coty Inc. (United States)

. Member of the Supervisory Board of DWS Investment GmbH (Germany)

. Vice-Chairman of the Supervisory Board of Hypo Real Estate Holding AG (Germany)

Table of Contents

Hermann Scholl	Age	69
Independent Director	First elected	<i>August 2004</i>
	Term expires	<i>2008</i>
	Principal occupation	Chairman of the Supervisory Board of Robert Bosch GmbH (Germany)
	Other directorships and appointments	. Member of the Supervisory Boards of Allianz AG (Germany) and BASF AG (Germany)
Gérard Van Kemmel	Age	65
Independent Director	First elected	<i>May 2003</i>
	Term expires	<i>2007</i>
	Principal occupation	Chairman of Novell for Europe, the Middle East and Africa
Bruno Weymuller	Age	56
Director	First elected	<i>May 1999</i>
	Term expires	<i>2008</i>
	Principal occupation	Executive Vice President, Strategy and Risk Assessment of Total SA
	Other directorships and appointments	. Director of Elf Aquitaine and Technip-Coflexip

During 2004, the Board of Directors met 12 times, with an overall attendance rate among Board members of 83%.

Table of Contents

Senior Management

Jean-François Dehecq

Chairman and Chief Executive Officer

Age: 65

Jean-François Dehecq has a degree from the Ecole Nationale des Arts et Métiers. He began his career as a mathematics professor and then served in the Army as a research scientist at the Nuclear Propulsion Department. From 1965 until 1973, he served in a variety of positions at Société Nationale des Pétroles d'Aquitaine (SNPA) before joining Sanofi as Managing Director in 1973. From 1982 to 1988, Mr Dehecq served as Vice President and Managing Director of Sanofi, before being appointed Chairman and Chief Executive Officer of Sanofi in 1988. Following the merger with Synthélabo in 1999, he was appointed to his present position. From 1998 to 1999, he also served as Managing Director of Health for the Elf Aquitaine group.

Gérard Le Fur

Senior Executive Vice President

Executive Vice President

Scientific and Medical Affairs

Age: 54

Gérard Le Fur has degrees in both pharmacy and science. He began his career at Laboratoires Pharmuka as Chief of Laboratories and later served as Assistant Director of Research and Development before joining Laboratoires Rhône-Poulenc as Director of Biology. He joined Sanofi in 1986 as Assistant Director of Research and Development, and was named Director of Research and Development in 1995, prior to being named Executive Vice President, Scientific Affairs in June 1999 following the merger with Synthélabo. In August 2004, he was appointed to Executive Vice President Scientific and Medical Affairs.

Hanspeter Spek

Executive Vice President

Pharmaceutical Operations

Age: 55

Hanspeter Spek graduated from business school in Germany. In 1974, he completed a management training program at Pfizer International, and then joined Pfizer RFA as a junior product manager. He served in various positions at Pfizer RFA, including as manager of the marketing division. Mr Spek joined Sanofi Pharma GmbH, a German subsidiary of Sanofi, in 1985 as Marketing Director, and served in various positions

Edgar Filing: SANOFI-AVENTIS - Form 20-F

in Germany and then at Sanofi in France, before being named Senior Vice President Europe following the merger with Synthélabo in 1999. He served as Executive Vice President, International Operations from October 2000, until January 2003, when he was named in charge of worldwide operations of Sanofi-Synthélabo. He was appointed to his present position in August 2004.

Jean-Claude Armbruster

Senior Vice President

Corporate Human Resources

Age: 59

Jean-Claude Armbruster has a diploma (DES) and a bachelor's degree (*maîtrise*) in private law, and a diploma (DES) in criminology. He also holds a barrister's practising certificate (CAPA). He joined Sanofi's legal staff in 1980 and served in a variety of positions, including Director of Human Resources at Sanofi, before being named as Senior Vice President, Corporate Human Resources in October 2000.

Gilles Brisson

Senior Vice President

Pharmaceutical Operations Europe (excluding France and Germany)

Age: 53

Gilles Brisson, a graduate of HEC (Ecole des Hautes Etudes Commerciales), began his career at Smith Corona. From 1980, he served in a variety of positions with companies that now form part of sanofi-aventis in areas including strategic planning, operations and corporate development. He was appointed Chairman of the Management Board of Aventis Pharma SA when Aventis was formed in 1999, in charge of France and then Europe operations. He was appointed to his present position in August 2004.

Table of Contents

Pierre Chancel

Senior Vice President

Global Marketing

Age: 48

Pierre Chancel, a pharmacist, is a graduate of the Institut de Pharmacie Industrielle in Paris. Since 2003, he has served as Managing Director of Aventis Operations in the United Kingdom and Ireland. Before being appointed to this position, he was in charge of global strategy development at Aventis, which led to the launch of the new diabetes treatment Lantus[®]. At Rhône-Poulenc, Mr Chancel served as Business Unit Manager in charge of products from 1997 to 1999 in the central nervous system, rheumatology and hormone replacement therapy fields. From 1994 to 1996, he was Marketing Director at Theraplix. He was appointed to his present position in August 2004.

Nicole Cranois

Senior Vice President

Communication

Age: 56

Nicole Cranois has a bachelor's degree (*maîtrise*) in literature from the Sorbonne, and degrees from the Ecole Française des Attachés de Presse and Sydney University (Australia). She worked for Elf Union and Elf France as a press executive, and served as the Director of Communication for the French Ministry of Family Affairs from 1981 to 1983. She joined Sanofi in 1985 as Director of Communication, and was appointed to her present position in June 1999 following the merger with Synthélabo.

Olivier Jacquesson

Senior Vice President

Business Development

Age: 55

Olivier Jacquesson trained as an engineer at the Ecole Centrale de Lille and has a degree from the Institut d'Administration des Entreprises (IAE). He joined the Roussel Uclaf group in 1976, serving as International Product Manager and then as Managing Director of subsidiaries in Belgium and Mexico before joining the Group's senior management in 1986. He took responsibility successively for various of the Group's operating divisions and co-ordinated the United States, Latin America and Asia regions, before being appointed in 2000 Managing Director of Laboratoire Aventis. At the start of 2004, he was named as Chairman of Aventis Pharma and Laboratoire Aventis, until December 2004. He was appointed to his present position in September 2004.

Jean-Pierre Kerjouan

Senior Vice President

Advisor to the Chairman

Age: 65

Jean-Pierre Kerjouan has a business degree from HEC (Ecole des Hautes Etudes Commerciales) and a law degree. From 1968 to 1981, Mr Kerjouan worked for Yves Rocher, first as Chief Financial Officer of Laboratoire Yves Rocher, then as Vice President and Managing Director of Yves Rocher. He joined Sanofi Pharma International in 1981 as Managing Director and served in a variety of positions at Sanofi, including Managing Director of Sanofi's beauty division and Company Secretary of Sanofi, before being appointed as Senior Vice President, Legal Affairs in 1996. He served in the same position at Sanofi-Synthélabo from May 1999 to December 31, 2003, before being appointed to his present position in January 2004.

Marie-Hélène Laimay

Senior Vice President

Audit & Internal Control Assessment

Age: 45

Marie-Hélène Laimay has a degree in business from a French business school (Ecole Supérieure de Commerce et d'Administration des Entreprises) and a DECS (an accounting qualification). She spent three years as an auditor with Ernst & Young before joining Sanofi in 1985. Mrs Laimay served in a variety of financial positions, including Financial Director of Sanofi's beauty division and Deputy Financial Director of Sanofi-

Table of Contents

Synthélabo following the merger with Synthélabo in 1999. From November 2000 to May 2002, she served as Vice President, Internal Audit, and from May 2002 to August 2004 as Senior Vice President, Chief Financial Officer, before being appointed to her present position.

Christian Lajoux

Senior Vice President

Pharmaceutical Operations, France

Age: 56

Christian Lajoux has a master's degree (DEUG) in psychology, a bachelor's degree (*maîtrise*) in philosophy and a master's degree (DESS) in personnel management from the Institut d'Administration des Entreprises in Paris. He served in a variety of positions at Sandoz, including Division Director, before joining Sanofi Winthrop in 1993. He then served in various positions, including Director of Operations and Managing Director of Sanofi Winthrop France, before being appointed Senior Vice President France just prior to the merger with Synthélabo in 1999. He served in that position until being named as Senior Vice President Europe in January 2003, and then as Senior Vice President Pharmaceutical Operations France in August 2004.

Jean-Claude Leroy

Senior Vice President

Finance

Age: 53

Jean-Claude Leroy has a degree in business (DESCAF) from the Ecole Supérieure de Commerce at Reims, France. He began his career at Elf Aquitaine in 1975 as an internal auditor, and worked in a variety of financial positions prior to joining Sanofi as the Financial Director of Bio Industries in 1985. Mr Leroy served in a variety of positions at Sanofi, including Financial Director, and was appointed as Senior Vice President, Finance following the merger with Synthélabo in 1999. He was named as Senior Vice President, Strategy, Business Development and Information Systems in October 2000. He was appointed Senior Vice President and Chief Financial Officer of sanofi-aventis in August 2004.

Gilles Lhernould

Senior Vice President

Industrial Affairs

Age 49

Gilles Lhernould has a diploma in pharmacy and a master's degree (DEA) in industrial pharmacy. He began his career as a manufacturing supervisor at Laboratoires Bruneau, and in 1983 joined one of Sanofi's subsidiaries where he managed production and later the factory. Mr

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Lhernould then served in a variety of positions within the Sanofi Group, including Director of Human Resources – Pharmaceuticals for Sanofi Pharma and Director of Operational Human Resources for Sanofi. Following the merger with Synthelabo in 1999, he served as Vice President in charge of integration and then Vice President of Information Systems before being named as Senior Vice President, Industrial Affairs in March 2001 and Senior Vice President Industrial Affairs in August 2004 of sanofi-aventis.

Heinz-Werner Meier

Senior Vice President

Pharmaceutical Operations, Germany

Age: 52

Heinz-Werner Meier holds a degree in mathematics and a doctorate in business management. He began his career in 1978 working in research and development for Siemens AG in Germany. He then worked as a scientific assistant in the Faculty of Business Management, Organization and Business Systems at Mannheim University. In 1985, he joined the Hoechst Group as Finance and Accounting Director. Mr Meier then served successively as Purchasing Director at Benckiser-Knapsack GmbH, Group Controller in the Pharmaceuticals Division of Hoechst AG, and Managing Director of Hoechst Marion Roussel. From January 2000 to May 2002, he was Chairman of Aventis Pharma Germany, and until August 2004 was Director of Human Resources, before being appointed to his present position.

Table of Contents

James Mitchum

Senior Vice President

Pharmaceutical Operations, Japan

Age: 52

James Mitchum holds an MBA from the University of Tennessee and a degree in business and mathematics from Milligan College. After qualifying as an accountant in the United States, Mr Mitchum began his career as an auditor with Coopers & Lybrand in the United States. He then served in a variety of financial and operational positions at Eli Lilly, and at other companies that now form part of sanofi-aventis. In addition to serving as Managing Director of Hoechst Marion Roussel Ltd. (United Kingdom) and Aventis Pharma Ltd. (United Kingdom), he has also served as Managing Director of Aventis Pharma Japan since 2002. He was appointed to his present position in August 2004.

Dirk Oldenburg

Senior Vice President

Legal Affairs and General Counsel

Age: 47

Dirk Oldenburg holds a doctorate in law and began his career first as an associate attorney and then as a partner with the firm of Pünder Volhard Weber Axter (now Clifford Chance) in Frankfurt. He joined the Hoechst group in 1998 as Director of Legal Affairs, before being appointed as Director of Legal Affairs for the Aventis Group in 1999. After acquisition of Aventis by Sanofi-Synthélabo in 2004, he was appointed Director of Legal Affairs for the sanofi-aventis group.

Antoine Ortolí

Senior Vice President

Pharmaceutical Operations, Intercontinental

(from January 4, 2005)

Age: 51

Antoine Ortolí is a graduate of the Ecole Supérieure de Commerce in Rouen, France, and of INSEAD. He also holds a law degree and an accountancy qualification. He began his career in 1980 as a financial and systems auditor with Arthur Young and Co. In December 1981, he joined the Sanofi Group, where he served in a variety of positions, including Finance Director of the Pharmaceuticals Division and Director of the Latin America region. Following the merger with Synthélabo in 1999, he was named as Vice President, Latin America, and then as Senior Vice President, Asia Middle East in June 2001. In June 2003, he took on the role of Vice President, Intercontinental region at Sanofi-Synthélabo. He was appointed to his present position in January 2005.

Philippe Peyre

Senior Vice President

Corporate Affairs

Age: 53

Philippe Peyre is a graduate of the Ecole Polytechnique, and began his career in management consultancy with Bossard before being appointed as a member of the executive committee of Bossard Gemini Consulting. In 1998, he joined Rhône-Poulenc Rorer as Senior Vice President Special Projects, and then served as Head of Integration at Aventis Pharma and as Company Secretary of Aventis and Senior Vice President, Business Transformation at Aventis. He was appointed to his present position in August 2004.

Bernard Reculeau

Senior Vice President

Pharmaceutical Operations, Intercontinental

(until January 4, 2005)

Age: 54

Bernard Reculeau is a graduate of the Ecole Nationale d Administration and the Institut d Etudes Politiques in Paris. He previously served as Senior Vice President and Managing Director of the Aventis Intercontinental Region, as well as holding a variety of senior management posts within the Rhône-Poulenc group. Before joining the Rhône-Poulenc group in 1984, Bernard Reculeau held a succession of posts at the French Finance Ministry and Industry Ministry. From August 2004 to January 2005, he served in sanofi-aventis as Senior Vice President Pharmaceutical Operations, International.

Table of Contents

Timothy Rothwell

Senior Vice President

Pharmaceutical Operations, United States

Age: 53

Timothy Rothwell holds a B.A. from Drew University (New Jersey) and a J.D. from Seton Hall University. He began his career in 1972 as a patent attorney at Sandoz Pharmaceuticals, where he worked in a variety of positions, including as Chief Operating Officer for U.S. Business, until he left Sandoz in 1989. From 1989 to 1991, Timothy Rothwell worked in marketing and sales at both Squibb Corporation and Burroughs Wellcome before returning to Sandoz in 1992 as Chief Executive Officer of Sandoz U.S. Pharmaceuticals, a post he held until 1995. From 1995 to 1998, Mr Rothwell served in a variety of senior management positions at Rhône-Poulenc Rorer, including President of Global Pharmaceutical Operations. He joined Pharmacia in 1998 where he served in a variety of positions, including Executive Vice President and President of Global Prescription Business before joining Sanofi-Synthélabo in May 2003. He was appointed to his present position in August 2004.

Pascal Soriot

Senior Vice President

Commercial Operations, United States

Age: 45

Pascal Soriot holds a doctoral degree in veterinary medicine from the Ecole Nationale Vétérinaire at Maisons-Alfort and an MBA from HEC-ISA (Ecole des Hautes Etudes Commerciales – Institut Supérieur des Affaires). Before taking up his current position at sanofi-aventis, he served in a similar position at Aventis. After being appointed by Roussel Uclaf in 1986 as Financial Controller for the Asia-Pacific region, he held various management positions in finance and marketing at companies that now form part of sanofi-aventis. He was appointed to his present position in August 2004.

David Williams

Senior Vice President

Vaccines

Age: 55

David J. Williams holds a degree in accounting and management from Scranton University in Pennsylvania. After working four years with Coopers & Lybrand, in January 1978 he joined the U.S. operating unit of Connaught Laboratories, Inc., serving in a variety of financial and marketing positions before being appointed in 1981, at the age of 31, to Vice President and General Manager of the U.S. Operations. In 1988, he was named President and Chief Operating Officer of Connaught Laboratories, Inc., a position he held for a decade. In 1998 he became President and Chief Operating Officer of Aventis Pasteur S.A., the vaccine business of Aventis. Since January 2003 he has served as Chairman, President and Chief Executive Officer of Aventis Pasteur S.A. In August 2004, he was named Senior Vice President, Vaccines of sanofi-aventis.

Table of Contents

As of December 31, 2004, none of these individuals had any principal business activities outside of sanofi-aventis.

The organization chart below shows the structure of the sanofi-aventis senior management.

Table of Contents**B. Compensation****Compensation of board members (other than our Chairman and Chief Executive Officer)**

Board members who were members of the sanofi-aventis Board of Directors prior to the Aventis acquisition received sanofi-aventis attendance fees in respect of the 2003 financial year¹, while former members of the Aventis Supervisory Board appointed to the sanofi-aventis Board of Directors by the General Meeting of June 23, 2004 received Aventis attendance fees in respect of the 2004 financial year. Compensation paid by the Group in 2004 is reported, including for Board Members appointed during the course of the year.

The table below shows amounts paid in 2004, broken down by type of compensation, to each member of the sanofi-aventis Board of Directors, including those whose term of office ended during 2004.

Name	Attendance		Total gross remuneration
	fees	Pensions	
	In euros		
René Barbier de la Serre	67,000		67,000
Jean-Marc Bruel	68,500	348,668	417,168
Robert Castaigne	31,000		31,000
Pierre Castres Saint Martin ²	31,000		31,000
Pierre-Gilles de Gennes ²	29,000		29,000
Thierry Desmarest	39,000		39,000
Jürgen Dormann	90,000	1,482,576	1,572,576
Lord Douro	47,000		47,000
Elf Aquitaine ²	31,000		31,000
Jean-René Fourtou	67,500		67,500
Hervé Guérin ²	31,000		31,000
Serge Kampf	72,500		72,500
Igor Landau	See table below		
L Oréal	47,000		47,000
Hubert Markl	62,500		62,500
Christian Mulliez ³			
Lindsay Owen-Jones	31,000		31,000
Klaus Pohle			
Hermann Scholl			
Gérard Van Kessel ⁴	35,250		35,250
Bruno Weymuller	43,000		43,000

Name	Base compensation	Variable compensation ⁵	Benefits in kind	Total gross compensation
Igor Landau	1,260,000	3,186,753	75,319	4,522,072

¹ Attendance fees allocated by sanofi-aventis in respect of a given financial year are paid during the subsequent financial year.

² Board member whose term of office ended in 2004.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

- ³ Permanent representative of L. Oréal until June 23, 2004, thereafter a Board member in his own right.
- ⁴ Board member since May 2003.
- ⁵ Variable compensation paid on the basis of performance during 2003 and, exceptionally, during the first half of 2004.

Table of Contents

In addition, under Mr. Igor Landau's contract of employment a payment of 13,017,357 was accrued in 2004 and paid to Mr. Landau at the beginning of 2005 consisting of contractual severance, a bonus installment and his salary through March 31, 2005.

Attendance fees allocated to board members for the financial year 2004 and payable in 2005 amounted to 871,500.

The fixed amount of sanofi-aventis fees is 15,000 per director (paid on the basis of time served in the event of a change during the period) plus a supplementary amount for each actual attendance at a meeting of :

the Board (4,000 per director and per meeting) ; and

the committees (4,000 per meeting and 6,000 per meeting for committee chairman).